



SAFETY MANUAL
MAGNETIC RESONANCE IMAGING UNIT
NEW YORK STATE PSYCHIATRIC INSTITUTE

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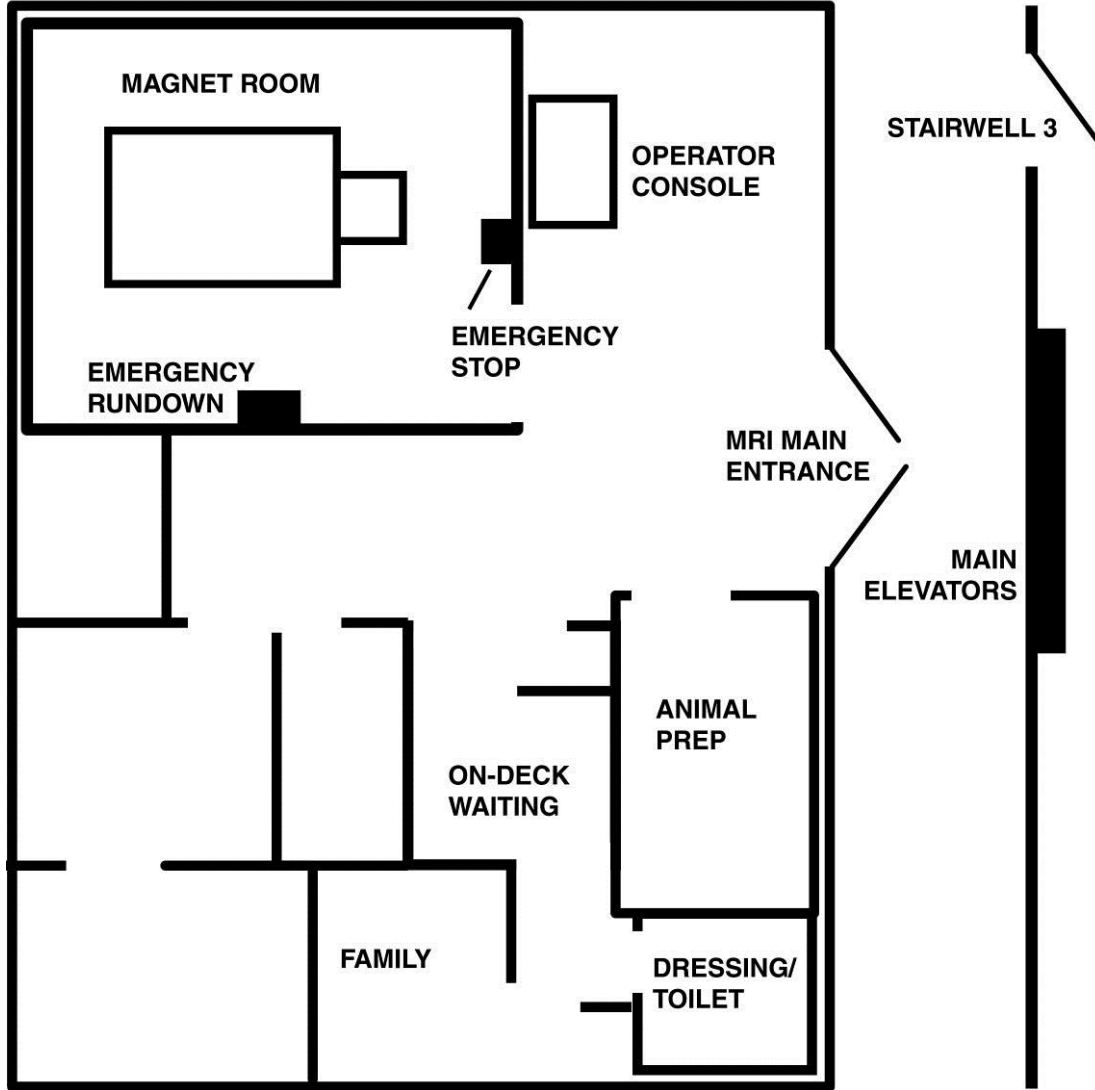
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II. NYSPI DIAGRAM OF MRI SUITE

NYSPI - MRI SUITE



III. SUMMARY OF EMERGENCY PROCEDURES FOR THE MRI UNIT

N.B. A glossary of terms is provided at the end of this manual

A. MEDICAL EMERGENCIES

1. x5555 will be dialed and the nature of the emergency along with the location will be relayed to the response team.
2. Subject will be evaluated by MRI personnel to establish the status of the emergency. Cardiac emergencies will elicit the medical emergency team from NYSPI and Presbyterian Hospital.
3. Emergency procedures will NOT be administered in the magnet room, and NO medical equipment is allowed in the magnet room. Instead, the MRI technologist will remove the subject immediately from the magnet room by undocking the MRI table and transported to an area within the department, where the emergency will be handled by the medical response team.
4. The magnet room door will be closed upon removal of the subject to avoid entry of any metallic objects.
5. Security officers will bring the crash cart from the NYSPI security desk.
6. If not already onsite, the principal investigator will be contacted and informed of the nature of the emergency. In addition, the emergency medical contact listed on the consent form, if different from the principal investigator will also be contacted.
7. All adverse events will be documented on an incident report. The IRB and the safety manager will be notified immediately via a telephone and within 48 hours in writing.

B. PSYCHIATRIC EMERGENCIES

1. x5555 will be dialed and the name and location of (unit and area) stating a psychiatric emergency is taking place.
2. If not already onsite, the principal investigator will be contacted and informed of the nature of the emergency. In addition, the emergency medical contact listed on the consent form, if different from the principal investigator will also be contacted.
3. The NYSPI Safety Officer will announce the emergency via the PA system. All available personnel will respond to the location.
4. Emergency procedures will NOT be administered in the magnet room. With the exception of plastic restraints, NO additional equipment is allowed in the magnet room. Instead, the MRI technologist will remove the subject immediately from the magnet room by undocking the MRI table and transported to an area within the department, where the emergency will be handled by the medical response team.
5. The magnet room door will be closed to avoid any entrance of metallic objects.
6. Under the direction of a nurse and the permission of a physician, restraints and seclusion of the subject will be implemented if deemed necessary.
7. Plastic restraints will be available in the MRI unit if needed. These should be used instead of restraints that have metal buckles.
8. All incidents will be documented and the IRB along with the safety manager will be notified immediately via a telephone call and within 48 hours of the incident in writing.

C. FIRE EMERGENCIES

1. The MRI technologist will immediately remove the subject from the magnet room and MRI unit and taken to safety via stairwell 3 or the loading dock. If the subject is on the MRI table, this can be moved through the exit doors without encountering stairs or elevators.
2. All doors will be closed to contain the fire.
3. x5555 will be dialed identifying type of fire and location of fire.
4. If the fire occurs in the magnet room, the fire will be extinguished using a non-ferrous fire extinguisher

D. LIQUID HELIUM

The superconducting magnet responsible for the permanent 3T magnetic field must be kept at a temperature of -269 degrees Celsius (-452.2 degrees Fahrenheit) in order to maintain its superconducting status. This is accomplished by circulation of liquid helium through a closed system surrounding the magnet and requires an adequate supply of liquid helium at all times. This is measured by the pressure within the closed system of the helium gas. After being filled by General Electric, this pressure is approximately 1200 Torr and under normal conditions (i.e., no leaks and a working water cooling system to keep the liquid helium chilled), the pressure drops approximately 2 Torr per day. The system becomes unstable if the pressure were to drop below 600 Torr. Therefore, under ideal circumstances, the system only requires refilling by GE every 300 days. To protect against any unanticipated problems such as a leak or failure of one of the cooling components, the pressure of the liquid helium is read by one of the MR physicists every weekday and noted on a calendar kept in the MR computer room. If any deviations from the expected pattern are noted, Dr. Kangarlu and Dr. Gerber are notified immediately and adequate measures taken to ensure that the liquid helium pressure does not drop to a dangerous level that would increase the chance of a quench.

E. QUENCH

"Quench" is the term used to describe a rapid loss of field strength in a superconducting magnet. During a quench, the magnetic current dissipates as heat, causing the liquid helium to boil off in gaseous form. MRI installations are designed with ventilation systems to handle the rapid boil off of liquid helium appearing as white clouds of vapor. These vapors can push oxygen out of the magnet room and cause asphyxiation, frostbite, or other injuries. An oxygen sensor located on the wall of the magnet room will detect any rapid change in the oxygen content of the magnet room and alert staff members inside and outside of the room of a potential problem. Impending magnet quenches are heralded by a loud noise, a warning message on the MRI console, or the tilting of the image on the screen of the MRI console. Should any of these occur, the MRI technologist will immediately remove the patient and all personnel from the magnet room.

Safety Procedures During a Quench In the event of a quench and sudden release of cryogens into the magnet room, the MRI technologist will perform the following procedures:

1. Using the intercom, **alert the patient to stay calm and remain on the table** until the technologist can gain access to offer assistance.
2. The magnet room **exhaust fan will be turned on and the magnet room door propped open** to promote air circulation.
3. If the door cannot be opened because of pressure from the cryogen released inside the scan room, the window to the magnet room will be broken using a plastic hammer placed by the window to relieve pressure, thereby allowing the technologist to gain entry into the room and assist the patient
4. The **patient will be transported out of the room**. When exiting the magnet room during a quench, it is best to stay near the floor where the oxygen will be more abundant.
5. **All personnel will evacuate the area** until the air is restored to normal.

F. EMERGENCY OFF

The **Emergency Off** button pictured below is located on the wall in the MRI magnet room and on the operator's console. It removes ALL electrical power from the MRI console and the patient table, including any power sources from the Uninterrupted Power Supply (UPS) devices. The effect of pushing the Emergency Off button is to turn off the entire MR system EXCEPT for the static magnetic field and the magnet rundown unit (described below), hence this DOES NOT PRODUCE A QUENCH. The button should be used only to stop a scan during a patient emergency or during a serious equipment fault or hazard, such as fire or water in the vicinity of the MR equipment. Only an experienced MRI Technologist, MRI physicist, or the Director of the MRI Unit are permitted to use the EMERGENCY OFF button if this type of emergency should occur.



G. EMERGENCY MAGNET RUNDOWN

The device for an **Emergency Magnet Rundown**, pictured below, allows for the rapid reduction of the magnetic field in about two minutes. It will also boil-off cryogenics and therefore, unlike the Emergency Off button, this button **WILL PRODUCE A QUENCH**. The button is located inside the magnet room on the left wall adjacent to the door. Only the MRI technologist, physicist, or director of the MRI unit is authorized to trigger the rundown. The rundown should be triggered to free someone pinned to the magnet or to remove a large ferromagnetic object captured in the magnetic field when injury to the subject is imminent. After triggering a rundown, the MRI technologist should:

1. Use the intercom to ***alert the patient to stay calm and remain on the table*** until the technologist gains access to the room to offer assistance.
2. ***Turn on the exhaust fan in the magnet room*** and ***prop open the magnet room door*** to promote air circulation.

3. ***Transport the patient out of the room.***

5. ***Evacuate all personnel from the area.***



H. PROCEDURE FOR POWER FAILURE

In the event of a power failure, the MRI unit has a battery back-up (UPS) system that lasts for up to two hours to permit an orderly shutdown of the MRI scanner console. If an MRI study is in progress, the patient will first be removed from the room by the MRI technologist either on the MRI table or by walking to stairwell 3 or the loading dock. Once patient safety is secured, the MRI technologist will return to the MRI suite and turn off all of the computers, thus preventing corruption of the software on the MRI scanner. The MRI unit and ancillary systems will remain off until the Engineering Department notifies the Director of the MRI Unit of adequate power return.

IV. SAFETY ORGANIZATION WITHIN THE MRI UNIT

The New York State Psychiatric Institute (NYSPI) Magnetic Resonance Imaging (MRI) unit is a research unit only, which with respect to safety, falls under the general guidelines of germane institutional policies at NYSPI, the New York State Office of Mental Health, and other relevant policy-making bodies of the state and federal governments.

A. THE MRI PROTOCOL COMMITTEE

The MRI Protocol Committee comprises individuals knowledgeable about experimental procedures in MRI, medicine, neuroscience, physiology, physics, and electronics and clinical issues involved in MRI scanning of adults, children, and infants. The Director of the MRI Unit will chair the Committee and will appoint the other committee members. The MRI Protocol Committee is responsible for the review, approval, and disapproval of all MRI research protocols that are to be conducted in NYSPI's MRI unit. This committee supplements, and in no way replaces, NYSPI'S Internal Review Board (IRB). MRI research protocols should be submitted first to the MRI Protocol Committee for approval prior to submission to the IRB. Research will not be conducted within the MRI department without approval of the MRI Protocol Committee and NYSPI's IRB.

B. THE MRI SAFETY COMMITTEE

The MRI Safety Committee comprises individuals knowledgeable about MRI physics and engineering, with a focus on safety issues specific to MR hardware. The MRI Safety Manager will chair the Committee and will appoint the other committee members in consultation with the Director of the MRI Unit. The MRI Safety Committee is responsible for review of new hardware and pulse sequences and questions about experimental safety, particularly when non-standard procedures are being proposed. The MRI Safety committee will work with the MRI Protocol Committee to review those protocols that do not include only routine procedures or use routine equipment. This committee supplements, and in no way replaces, the MRI Protocol Committee and NYSPI'S Internal Review Board (IRB). Research with non-standard procedures will not be conducted within the MRI department without approval of the MRI Safety Committee and NYSPI's IRB.

The MRI Safety Committee is responsible for safety within NYSPI'S MRI department and will perform the following safety-related tasks:

1. Review all non-standard protocols for adherence to the provisions of the MRI Safety Policy.
2. Review the safety manual periodically, revise the MRI Safety Policy as needed, and report any changes to the IRB and Environment of Care Committees.
3. Appoint an MRI Safety Manager, who must be a member of the MRI Safety Committee.
4. Convene as needed, but no less than 6 times per year.
5. In the event that an unsafe condition arises, or if a safety policy has been violated, the MRI Safety Committee has the authority and responsibility to revoke approval of the protocol involved until the condition is corrected. The MRI Safety Manager has this authority *pro tempore*.

C. MRI SAFETY MANAGER

The MRI Safety Manager, a member of the MRI Safety Committee, is appointed by the Director of the MRI Unit. He/she is experienced and knowledgeable about the operation of the MRI scanner, safety hazards, and safety policies of the MRI unit and NYSPI. The Safety Manager has the authority to suspend any activity in the MRI Unit that in his/her judgment violates the safety policies of the MRI Safety Committee or NYSPI, or that otherwise constitutes an unsafe condition. He/she may transfer this authority to an approved operator of the facility. The Safety Manager will perform the following safety-related tasks:

1. Ensure that the safety policies of the MRI Safety Committee are followed during the execution of approved MRI research protocols.
2. Advise the MRI Safety Committee about needed changes in Safety Policy.
3. Coordinate classes concerning safe conduct of research in the MRI Unit.
4. Verify that any personnel involved with any function within the MRI Unit have attended the aforementioned MRI safety classes.
5. Maintain a permanent file of incident reports and any corrective actions taken.
6. Ensure adequate distribution of the manual governing safety within the MRI Unit.
7. Maintain safety records of investigators within the MRI Unit.
8. Report monthly to the Chair of the MRI Safety Committee.
9. Remain current on all new governmental and non-governmental policies and recommendations regarding MRI safety.
10. Report to the Environment of Care Committee (EOC) and provide copies of all incident reports to the EOC on a quarterly basis.
11. Report employee accidents to the NYSPI Safety Department.

D. OPERATORS OF THE MRI SCANNER

A qualified MRI operator will be responsible for performing all MRI procedures. He/she must have the following qualifications:

1. An academic degree of M.D, a Ph.D. in a relevant area, or else be a licensed MRI technologist
2. Have been approved by the MRI Safety Committee.
3. Have completed successfully a formal class on safety conducted by the MRI Safety Manager
4. Have completed hands-on training on the NYSPI MRI scanner under the supervision of an experienced MRI technologist.
5. If an MRI Technologist, the operator will have satisfactorily completed a formal class on Radiological procedures, will have current license by the American Registry of Radiological Technologist

V. GENERAL SAFETY CONSIDERATIONS

FOR MRI SCANNING AT 3.0 TESLA

NYSPI's General Electric Signa 3.0 Tesla MRI scanner has been approved by the Food and Drug Administration (FDA) for human and animal use. It will be used solely for research purposes that will involve animal and human subjects, as well as MRI phantoms (containers filled with gelatinous materials or chemicals). NYSPI's IRB has jurisdiction in all research involving human subjects

Incidents are to be reported to NYSPI's Director of Quality Management within 24 hours by telephone at 212-543-5273 and in hard copy on the Incident Reporting Form. Incidents are to be reported following NYSPI's Central Policies & Procedures Manual, and on p. 20 of this safety manual.

A. GENERAL SAFETY PROCEDURES IN THE MRI UNIT

1. All research subjects will be evaluated by the principal investigator, or designee, as to their physical and mental status before entering the MRI Unit
2. All female human subjects who are potentially child bearing (10-60 years old) are screened with a urine pregnancy test prior to entering the scan room by qualified personnel and evidence of a negative test provided to the scan technologist.
3. All individuals will undergo screening for metallic objects before entering the magnet room, and those with critically implanted magnetic objects (i.e., aneurysm clips, pacemakers etc.) will not be allowed in the room*.
4. All research subjects will be attended at all times while present in the MRI Unit
5. No human or animal research will be performed within the MRI Unit without prior approval of the NYSPI's IRB and the MRI Safety Committee
6. All human subjects (or legally authorized representative) will sign an IRB-approved informed consent form before entering the magnet room of the MRI Unit
7. When the MRI scan is in progress, subjects will be given a signaling device to hold so that he or she can alert the MRI technologist in case of an emergency or discomfort
8. All subjects will be visualized either via direct eye contact or via a camera system while the MRI scan is in progress

* The MRI technologist will observe the following steps for all subjects and their accompanying personnel before they enter the magnet room (1) The screening sheet must be either completed or carefully reviewed by the MRI technologist, in addition the (2) subject screening sheet must be carefully read by the PI or his/her designated assistant and their satisfaction with the answers be conveyed to you. Both MRI technologist and the PI must agree that there are no contraindications for introduction of the subject into the magnetic field. (3) The subject must undergo careful hand-scanning with Magna scanner prior to admission in the magnet room. During this stage the hand-held scanner should be in contact with the subject's attire and his/her entire body surface be scanned. Any indication of the presence of metals in the body must be considered as a contraindication unless the source is either found outside the body and removed, or until the source is identified and a valid reason for the MR compatibility of the source is presented by the subject or the study PI.

B. MRI-SPECIFIC RISKS

The risks of MRI scanning can be classified into one of four categories, those associated with a) Acoustic Noise Levels, b) Gradient or Time-Varying Magnetic Fields, c) Radiofrequency (RF) Magnetic Fields, and d) Static Magnetic Fields.

a. Acoustic Noise The acoustic noise associated with MRI imaging is related to the mechanical movement of the gradient coils during the scanning process.

FDA Guidelines: "The acoustic noise levels associated with the device must be shown to be below the level of concern established by pertinent Federal Regulatory or other recognized standards setting organizations. If the acoustic noise is not below the level of concern, the sponsor must recommend steps to reduce or alleviate the noise perceived by the patient." Current FDA guidelines follow the regulations of the International Electrotechnical Commission (IEC) Standard 601-2-33, which stipulate that for MR equipment used in medicine, hearing protection is required when the system can produce acoustic sound levels above 99 dBA and that the protection should be able to reduce noise levels to below 99 dBA.

The FDA has approved systems for which noise levels have been quantified, ranging up to 105 dB RMS for scanners operating at field strengths of 1.5 Tesla. It is important to note that the static magnetic field strength is only one factor, and not necessarily the most important one, in determining acoustic noise. Among the factors listed above, the design and construction of the gradient coils plays a major role in the noise level that MRI scanning produces. Therefore, noise levels are not necessarily greater when scanning at 3.0 T compared with 1.5 T field strengths. It is nevertheless possible that, in some circumstances, our system could produce noise levels higher than 99 dB, as do many clinical systems operating at lower field strengths.

Summary of Risks: The acoustic noise levels perceived by human subjects when undergoing MRI examination in our 3.0 Tesla magnet constitutes a non-significant risk; specifically, our system will not be operated in a way that will present more noise to human subjects than is recommended by the FDA.

Ensuring Safety From Acoustic Noise As suggested by the FDA, we will take steps to reduce or alleviate the noise levels experienced by subjects in this protocol. This will be accomplished by one of two methods:

1. Use disposable earplugs
2. Use acoustically shielded headsets

b. Peripheral Nerve Stimulation The time-varying magnetic fields used in MRI can, in some instances, induce stimulation of peripheral nerves, thereby producing sensations such as 'twitching' or 'tingling'. In very rare instances, this nerve stimulation can be painful. Nerve stimulation is particularly likely when subjects are physically positioned in a way that increases the likelihood of inducing stimulation, such as with hands clasped or arms folded. It should be noted that the parameter of interest here, dB/dt (the rate of change in the magnetic field per unit time), is not a function of the strength of the static magnetic field, so evaluating risk in a 3T MRI scanner involves the same considerations as evaluating other MRI systems operating at lower magnetic field strengths (i.e., the same issues apply to all the commercially available, FDA approved scanning systems). Thus, it is the *gradient system only* that needs to be evaluated to determine the risk of producing nerve stimulation.

FDA Guidelines: The FDA Guidance of 1995 was developed specifically to consider the fact that many clinical systems were capable of exceeding levels of dB/dt that could produce nerve stimulation. It was originally considered that a warning level should be implemented to guard against peripheral nerve stimulation, but the FDA finally concluded that: '*... this warning level is not considered critical since there are no harmful effects associated with mild peripheral nerve stimulation*'. The current guidelines therefore include monitoring procedures to help avoid painful peripheral nerve stimulation, and without specific dB/dt limitations.

Summary of Risks The gradients used in our 3.0 Tesla MRI system will typically be operated at levels below those considered to be negligible according to FDA guidelines. Our system, like most commercially available, FDA-approved systems, does have the capacity to exceed this level, but it will include the same safeguards that are included in

other FDA-approved clinical systems. Furthermore, policies and procedures will be implemented according to FDA guidelines to avoid the possibility of painful peripheral nerve stimulation. Therefore, in all circumstances the system will be operated in a way that poses non significant risk to the participant.

Ensuring Safety from Peripheral Nerve Stimulation

1. All consent forms for studies that might induce peripheral nerve stimulation will provide this information.
2. A record of dB/dt value will also be included with the imaging data to help in an analysis of levels of peripheral nerve stimulation possibly perceived by subjects.
3. Detailed calculations of the changes in magnetic field over time of which the gradient system is capable will be calculated, and conservative values will be selected as limits that will be used to determine when special additional monitoring is indicated. In these cases, monitoring procedures recommended by the FDA will be used.
4. The gradient switching times and strengths will be monitored together with the routine assessment of all electrical components of the system.
5. All MR technologists will receive special training to prevent peripheral nerve stimulation.
6. Before any scanning procedure that might stimulate peripheral nerves, a technologist will:
 - o Inform the subject that peripheral nerve stimulation may occur
 - o Describe the nature of the sensation to the subject
 - o Instruct subjects not to clasp their hands, since this may create a conductive loop which will increase the possibility of stimulation
 - o Maintain constant verbal contact with the subject
 - o Instruct subjects to inform the MR technologist if they experience discomfort or pain
 - o Terminate the scan if the subject complains of discomfort or pain
 - o Complete a report of any incidents involving severe discomfort or pain, including a description of the associated circumstances (imaging parameters, dB/dt value, level of pain, etc.), and submit this report immediately both to the IRB and to the MRI Safety Committee

c. Tissue Heating MRI scanning induces some heating of body tissues. This specific absorption rate (SAR) that determines heating is the amount of radiofrequency (RF) energy deposited (typically by a coil or "helmet"-like apparatus placed over the subject's head) per unit volume of tissue per unit time. RF energy in MRI examinations is not a function of the strength of the static magnetic field. Rather, the Specific Absorption Rate (SAR) for RF radiation is related to the amplitude of RF power, the duration of the RF pulse, the type of RF coil used, the frequency of RF radiation, the resistivity of the tissue, the configuration of the anatomical region being examined, and several other parameters.

FDA Guidelines: "The following are levels of concern at which the reviewer shall exercise appropriate actions to ensure that the safety of the device is substantially equivalent to a predicate device: A) If SAR # 0.4 watts per kilogram (W/kg) whole body; and if SAR # 8.0 W/kg spatial peak in any 1 gram of tissue; and if SAR # 3.2 W/kg averaged over the head: **below level of concern**. Or B) If exposure to radiofrequency magnetic fields is insufficient to produce a core temperature increase in excess of 1°C and localized heating to greater than 38°C in the head, 39°C in the trunk and 40°C in the extremities: **below level of concern**. The parameter SAR cited above must be

shown to fall below either of the two levels of concern by presentation of valid scientific measurement or calculation evidence sufficient to demonstrate that SAR is of no concern."

It should be noted that this guideline is based on the calculation of a system that has no thermoregulatory response, and thus it is a very conservative estimate compared with the temperature change that would be experienced in any living subject. Normal diurnal temperature variations in humans, for example, are about +/-1°C from the normal set point 37°C, and healthy people with normal thermoregulatory responses can easily dissipate any excess (or, in this instance, deposited) heat by increasing their peripheral blood flow or sweat rate. Thus, the heating effect of MRI with the SARs used in accord with these guidelines is extraordinarily unlikely to cause any acute effects in healthy human subjects.

Summary of Risks: Because all experiments performed on the 3.0 Tesla system will comply with FDA guidelines with regard to SAR, and because appropriate RF power safety checks are in place, this criterion for classification of NSR is satisfied.

Ensuring Safety from Tissue Heating Risks The magnitude of temperature increase during MRI scanning is minimal. Increases are always within FDA guidelines, which include core temperature increases less than 1°C, as well as localized heating to less than 38°C in the head, 39°C in the trunk, and 40 °C in the extremities. Our 3.0 Tesla system has in place a means to monitor RF power levels and ensure that energy deposition is sufficiently low to stay well within these guidelines for temperature increases. First, a "system security" unit is employed to integrate the output of the RF amplifiers. This integration takes into account the amplitudes and duty cycle of the transmitter. If system security detects an output that might exceed the guidelines noted above, it automatically shuts down the entire RF power system. Secondly, all pulse sequences are evaluated, based on calculations and sound scientific measurements, to ensure that SAR remains within FDA-approved guidelines, prior to their use in humans. Any experiment performed on our 3.0 Tesla system will comply with all FDA guidelines with regard to RF power deposition. Proper and routine monitoring of all RF electronics (e.g., coils, transmitters, system security, etc.) will be performed on a regular basis. All pulse sequences will be evaluated (by calculation and by valid scientific measurement) prior to use in humans.

d. Static Magnetic Fields The possible risks of static magnetic fields have received much attention in the lay press, but scientific consensus on these risks has yet to be fully reached. The FDA has deemed that systems operating at 8.0 Tesla or less do not pose a significant risk. Moreover, experience with thousands of clinical studies over the past decade, and with multiple human investigations carried out at higher field strengths over this period, have not revealed risks of exposure to higher static magnetic fields. The most significant risk associated with static magnetic fields is that ferromagnetic objects, such as aneurysm clips or heart valves, can interact with the magnetic field of an MRI scanner, causing the device to malfunction or to move, and injuring the subject. For some patients, rapid head movement while in the magnetic field may cause dizziness, vertigo, or a metallic taste in their mouth.

FDA Guidelines: "Studies conducted at 8T or less are not considered significant risk" (FDA Center for Devices and Radiological Health, memorandum 7-14-03).

Summary of Risks: This category of risk applies to work conducted around superconducting magnets of any kind (including standard clinical diagnostic MRI units). It is not unique to our 3.0 Tesla facility. The MRI facility will maintain a safety policy to safeguard subjects and staff members from these incidental risks. Systems with static magnetic field less than 8 Tesla have been considered to represent a nonsignificant risk (NSR) by the FDA. The static magnetic field of our system (3.0 Tesla) is therefore to be classified as posing NSR to human subjects.

Ensuring Safety from Static Magnetic Field Risks The minimization of risks associated with the static magnetic field of 3.0 Tesla is mainly related to incidental risks (see below). These risks are the same as in other commercially available clinical systems, and like other clinical MRI centers, our facility will incorporate a complete range of procedures, including:

1. Assure the security of the restricted access area. Entrance doors to the MRI department will be kept closed and locked at all times. Spring locks and door returns are installed on the doors to restricted access areas. Access to the MRI suite will be tightly controlled, allowing access for only personnel and research subjects who have legitimate reason to be there. Doors to the MRI Unit will be securely locked, with only MR technologists, physicists, or physicians controlling entry of people and equipment into the MRI Unit.
2. Entry-ways to the MRI Unit will be labeled with clear visible signs warning of the presence of the magnetic field and the exclusion from entry by individuals with implanted metal objects such as prostheses, pins, clips, IUD's, etc.
3. The MRI Technologist will conduct careful screening of potential subjects before they enter the magnet room
4. A metal detector will be positioned at the doorway leading into the magnet room
5. To minimize the potential for dizziness or a metallic taste, it is recommended that the patient remain still while in the region of high static magnetic field.

e. Incidental Risks The physical confinement and isolation produced by the scanner could cause mild to moderate emotional distress, although in our extensive past experience, subjects generally tolerated the procedures remarkably well.

Ensuring Data Safety

1. All subjects will be able to communicate directly with technologists and study staff to inform them of any emotional or physical distress during the scanning procedure. If they wish, the scan will be terminated immediately and the subject will be removed from the scanner.
2. All MRI data will be stored behind firewalls at NYSPI

VI. SPECIFIC HAZARDS WITHIN THE MRI UNIT

A. ELECTRICAL HAZARDS

1. The MRI scanner will be evaluated regularly for electrical hazards by the General Electric Field Engineer, as detailed in the service agreements with the MR system manufacturer
2. All modifications to the equipment will be performed only by the General Electric Field Engineer and will be properly evaluated in terms of electrical safety
3. Safety tests will be carried out on a regular basis by the General Electric Field Engineer with regard to radiofrequency and magnetic field levels, as detailed in the service agreements with the MR system manufacturers. After safety tests are completed, the service engineer will leave a comprehensive service report relating all results and action taken to restore any faults in MRI system.
4. The Material Safety Data CD ROM is located in the MRI Unit.

B. CRYOGEN HAZARDS

A superconductive magnet in the MRI scanner uses cryogenics to supercool the electrical conductor that creates the magnetic field. Temperatures as low as -269°C (-452°F) are achieved to create the proper superconducting environment within the magnet. A quench, which is a sudden boil-off of the entire volume of cryogenic liquid, causes a rapid loss of the static magnetic field.

Cryogenics come in large vacuum containers called "Dewars". Liquid helium is generally used for cooling purposes, although some service procedures also require liquid nitrogen. Nitrogen Dewars weigh from 400 to 500 pounds when full. Helium Dewars weigh from 700 to 800 pounds. In addition to large Dewars, there may be smaller helium gas cylinders present. This helium gas is used to fill the magnet to the correct cryogen levels. The cryogenics boil off as they cool the magnet wires and must be replenished periodically by qualified personnel. Contact with the cryogenic liquids or gas could result in severe frostbite, and care is needed when in proximity to these substances. Furthermore, leaking helium or nitrogen gas will displace oxygen from the room. An ambient air oxygen concentration of less than 17% to 18% is not sufficient for human respiration, and therefore a large cryogen leak or quench of the magnet is dangerous to humans and animals in the room.

Safety Procedures:

- All dewars and gas cylinders must be non-magnetic
- Dewars should be stored in a well-ventilated area
- Gas cylinders should be stored upright and secured to the wall with a chain with a metal protective cap in place (if the cylinder falls over or the valve is knocked off, the container may act like a rocket, as a full cylinder has enough power to penetrate walls)
- The valves of Dewars and cylinders should not be tampered with
- Because cylinder caps may be metal, they should be removed before bringing the cylinder into the magnet room

- If possible, all personnel should stay out of the magnet room when a qualified service engineer is filling cryogens in the magnet. If personnel from the MRI Unit must be present, they must wear proper gloves, a face shield, and ear protectors
- A qualified service engineer from General Electric (1 800-437-1171) should be present any time cryogens are transported within the hospital or added to the magnet
- Flammable material must not be brought near the cryogen containers
- The wearing of protective clothing is essential during all work performed with liquefied cryogens. Such clothing consists of:
 - o Safety gloves
 - o Work gloves
 - o Face shield
 - o Laboratory coat or overalls (cotton or linen)
 - o Non-magnetic safety shoes
 - o Non-magnetic eye-glasses, if required
- The Material Safety Data (MSD) information for cryogens is located on a CD ROM at the console of the MRI Unit.

C. FIRE HAZARDS

General Safety Procedures:

1. Necessary equipment (fire extinguishers, etc.) will be stored within the MRI Unit to manage all classes of fire. All equipment will be non-magnetic.
2. To protect against the possibility of fire, no flammable liquids in excess of five gallons will be brought into the MRI Unit.

Fire with Operators On-Site:

1. The Operator will know all of the fire emergency related procedures, including a patient evacuation plan, and its proper execution. Stairwell #3 and the loading dock, located on the service level, have been assigned as the point of exit for evacuation during a fire.
2. The MRI technologist, Safety Manager, or Director of the MRI unit will evaluate the need for an emergency quench of the magnet.
3. In the event of a fire requiring outside response, the Safety manager, MRI technologist, or Unit Director will quench the magnet if ferromagnetic equipment must enter the MRI magnet room. They will direct entry and exit to the magnet room until the magnetic field reaches zero.

Fire During Off Hours or No Operators On-Site:

1. Contact the Director of the MRI Unit, the MRI Safety Manager, or the MRI Technologist immediately. These phone and pager numbers are posted immediately to the left of the scanner console and at the front of this manual.
2. Once contacted, the Director of the MRI Unit, the MRI Safety Manager, or the MRI Technologist will instruct fire fighting personnel and Security staff as to the means of entry to the MRI Unit and to the proper means of quenching the magnet, if necessary.
3. If, for any reason, these individuals cannot be contacted, the Director of NYSPI should be contacted for the decision to quench the magnet.
4. For purposes of access in an emergency, the NYSPI Security Department will have a key to the MRI Unit.

D. INFECTION CONTROL PROCEDURES FOR HUMAN STUDIES

1. Hands will be washed between subjects.
2. The MRI table and head rest will be covered using exam paper sheets. Sheets will be discarded after each subject.
 3. All contaminated products will be discarded in the red bag waste.
 4. The sharps container will be removed if 3/ 4 full.
 5. The magnet room table and headrest will be wiped with a Sani-wipe at the end of the day.

E. SAFETY PROCEDURES FOR MRI EXPERIMENTS INVOLVING ANIMALS

1. Prior to the use of the NYSPI MRI scanner, an animal use protocol must be approved by the Institutional Animal Care and Use Committee (IACUC) at NYSPI and Columbia Presbyterian Medical Center, as well as by the MRI Safety Review Committee. In addition, a letter of authorization that designates the ranking official has to be on file in the (IACUC) office.
2. The use of the rhesus monkey presents potential risk to humans. This risk is related to herpes B virus. Although rare, it could be fatal for humans. All monkeys housed in NYSPI are negative for herpes B virus; however, the potential risk for contracting the virus is still a concern. All precautionary measures should be taken to assure maximum safety. An emergency kit will be transported from NYSPI with the monkey to the MRI suite. The emergency kit will contain betadine scrub and eye wash to be used in case of an emergency. A copy of the monkey bites and scratch protocol will be enclosed in the emergency kit. All personnel involved in the procedure have attended the NYSPI OHS seminar.
3. The principal investigator will be responsible for making arrangements with the MRI administration for the use of the facility and the necessary technical expertise.
4. In case of a bite or scratch, go to the CPMC emergency room with a copy of the bite and scratch protocol located inside the emergency kit.
5. Animals will be transported to and within the MRI Unit in a way to minimize contact with patients and hospital staff.
6. Prior to being transported to the MRI suite the rhesus monkey will be kept NPO and anesthetized to ensure an uneventful delivery.
 7. A trained member of the study will accompany the monkey and will be in the MRI Unit at the time of the procedure. This will be accomplished by using a suitably sized cage for each individual animal that will be covered with sheets. This will be covered by the NYSPI animal care facility.
 8. Universal precautions will be used when animal studies are being performed. Universal precautions will include the wearing of gloves, goggles, face mask, shoe covers, and gowns, all of which will be discarded in the red waste container.
 9. After scanning of the animal is completed, the magnet room table, headrest, and all objects used during the scanning procedure will be cleaned with Sani wipe and Clidex.
 10. All sheets, pads, or other material, such as syringes or I.V. tubing, etc will be disposed of in the "red bag" biohazard container.
 11. All of the surfaces that come into contact with the animal will be disinfected using Clidex.

To ensure proper procedural adherence, a copy of the animal safety protocol will accompany the animal, as will the protocol guidelines that are to be followed regarding infection control before, during and after the MRI procedure. These protocols will be signed by the MR technologist on site after the experiment is completed.

F. SAFETY OF HOUSESTAFF AND SECURITY PERSONNEL

1. NYSPI's security, engineering, and housekeeping personnel will view a MRI safety video followed by a question and answer session. After the question and answer session, a quiz will be given. This procedure will ensure staff safety and the proper safety procedures that should be followed in the MRI Unit.
2. Housekeeping will not have access to the magnet room of the MRI unit.
3. Security staff will have access to the magnet room within the MRI department only under the supervision of the MRI Unit Director, MRI Safety Manager, or MRI technologist.
4. In the event of an emergency, the Security Officer will have on file a telephone number for the MRI Unit Director, MRI Safety Manager, and MRI technologist. Once contacted, the safety manager or MRI technologist will advise the Security Officer in safe methods to access the facility and the safety procedures to follow once the restricted area is entered.

G. INCIDENT REPORTS

It is the duty of the MRI Safety Manager at NYSPI to report all violations of safety procedure and accidents to the MRI Safety Committee. The MRI technologist will document any the following incidents in writing and immediately submit this report to the Safety Manager.

1. Incidents in which any person was injured.
2. Incidents requiring the emergency quench of the magnet.
3. Incidents involving damage to MRI and ancillary equipment.
4. Conditions that constitute a safety hazard.
5. Incidents in which an approved protocol was not followed, causing an unsafe condition.

The safety manager is required to report these various categories of incidents within the following time periods:

- o Incidents 1 and 2 above: To the Chair of the MRI Safety Committee, the MRI Unit Director, and the Environment of Care Committee immediately
- o Incidents 3 and 4 above: To the Chair of the MRI Safety Committee, the MRI Unit Director, and the Environment of Care Committee within 24 hours.
 - o Incident 5 above: To the MRI Safety Committee at its next meeting
 - o Any incident involving human subjects must also be reported to the Institutional Review Board within 24 hours
 - o The MRI safety Manager will provide copies of all incident reports to the Environment of Care Committee on a quarterly basis.

Nothing in the foregoing is to be interpreted as preempting the legal and institutional responsibilities of the NYSPI's Institutional Review Board, regulations of the New York State Office of Mental Health, or such entities and agencies as have purview over safety and research procedures at NYSPI.

VII. GLOSSARY

Cryogen: A superconductive magnet in the MRI scanner uses cryogenics to super-cool the electrical conductor that creates the magnetic field.

Exclusion Zone: The magnet room and the MRI suite are considered the exclusion zones. All ferrous equipment must remain outside exclusion zone.

Ferromagnetic vs Ferrous: Ferromagnetic, a substance that is ferromagnetic and has a large positive magnetic susceptibility (e.g. iron). Ferrous items can possess intrinsic magnetic fields and react strongly in an applied magnetic field. (Iron, Nickel, Cobalt).

Peripheral Nerve Stimulation: Sensations such as 'twitching' or 'tingling', usually in an arm or leg. In very rare instances, this nerve stimulation can be painful.

Quench: Quench is the term used to describe a rapid loss of field strength in a superconducting magnet. During a quench, the magnetic current dissipates as heat and causes the liquid Helium to boil off in gaseous form. MRI installations are designed with ventilation systems to handle the rapid boil off of liquid helium.

Restricted Access Area: All of MRI Unit except patient waiting area.

Security Zone: The Security Zone warning sign will be posted on the entrance to the magnet room to alert personnel to the high magnetic field and warn not to bring ferromagnetic objects into the magnetic room.

Static Magnetic Field: Static magnetic fields are measured in Gauss (G) or Tesla (T), with 10,000 G being equal to 1 T. For comparison's sake, the earth's magnetic field varies from approximately 0.3 to 0.7 G between the equator and the poles, respectively, while a small refrigerator door magnet may be used as strong as 150 G to 250 G. The strengths of the static magnetic fields used in clinical and research MR systems for imaging and/or spectroscopy range 0.012 T to over 10 T (100,000 G). According to the most recent recommendations and guidelines provided by the United States Food and Drug Administration (FDA), clinical MR systems are permitted to function on a routine clinical basis at static magnetic field strengths of up to 4.0 T.

Tissue Heating: MRI scanning induces some heating of body tissues.

Unrestricted Area: The unrestricted area in the MRI suite is the patient waiting room