

**SAFETY MANUAL
MAGNETIC RESONANCE IMAGING UNIT
NEW YORK STATE PSYCHIATRIC INSTITUTE**

CONTACT INFORMATION FOR SAFETY PERSONNEL IN THE MRI UNIT

1) Rachel Marsh, Ph.D.
Director, MRI Research Program
1051 Riverside Drive
New York, NY 10032
O: (646)774-5774

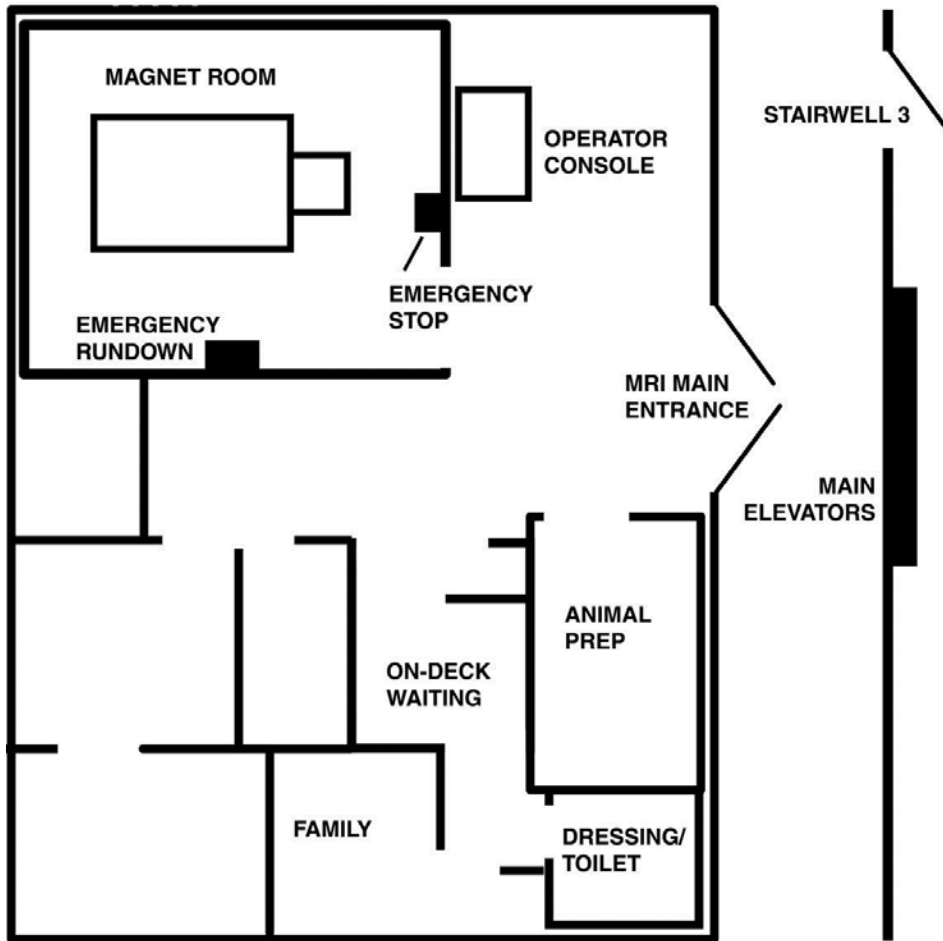
2) Alayar Kangarlu, Ph.D.
Director of MRI Safety
O: (646)774-7256
C: (914)659-4967
Alayar.kangarlu@nyspi.columbia.edu

3) Larry Kegeles, M.D.
Medical Director, MRI Unit
O: (646)774-5560
Larry.Kegeles@nyspi.columbia.edu

4) Claudio Cabezas
GE Service Engineer
C.516-987-7755
V.M 1.800-257-2878 Ext225837
claudio.cabezas@med.ge.com

DIAGRAM OF THE NYSPI MRI SUITE

NYSPI - MRI SUITE



OVERVIEW

The purpose of this manual is to provide an overview of safety procedures at the New York State Psychiatric Institute (Henceforth referred to as NYSPI) for human and animals studies at the MRI Research Program and its facilities. The program is equipped with a 3 Tesla GE Signa Premier body scanner. The system is equipped for high-definition 2D and 3D structural scans, Echo Planar Imaging, Diffusion Imaging, and MRS, as well as other in-development MR modalities.

The scanner is open from 8am to 8pm Monday through Friday, and 9am-5pm on Weekends as needed.

Procedures for the unit are outlined by topic, and should be reviewed in their entirety by all Investigators and Staff before beginning a study at NYSPI.

NYSPI's General Electric Signa Premier 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, with the exception of svc contracts, and NHP scans, which fall under supervision of the IACUC

OPERATORS OF THE MRI SCANNER

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

An academic degree of B.A. or higher in a relevant area, or else be a licensed MRI technologist.

Have been approved by the director of the MRI Safety and Director of the MRI Research Program

Have completed successfully a formal class on safety conducted by the Director of MRI Safety

Have completed hands-on training on the NYSPI MRI scanner under the supervision of an experienced MRI Operator.

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 Technologists.

THE MRI SUITE AND SAFE ZONES

Only MRI Faculty and Staff, and research Faculty and Staff who have successfully completed MRI safety training as well as been given a "Green Badge" by the unit may enter the magnet room. Under no circumstances should any research staff enter the magnet room without first notifying the scanner operator.

To obtain a green badge, faculty and staff must attend a safety training class given by the director of MRI Safety, and then must attend no less than three (3) scan sessions as verified by the MRI unit administrator.

Faculty and staff who have completed the training but have not yet obtained green status may be present in the operator console area, but may not enter the magnet room. Untrained staff may not be present in the console operator area, but must remain in the family waiting area and/or prep areas. All subjects and their families and companions must remain in the family waiting and/or prep areas at all times unless escorted by trained faculty or staff.

Food and drink are allowed in the console area but **ARE NOT** allowed in the magnet room.

SUMMARY OF PARTICIPANT PROCEDURES FOR MRI

When screening participants:

- Non-removable implants (joint replacements, screws, surgical staples, etc.) must be accompanied by a letter from the operating surgeon or medical facility stating the composition and/or brand and model of the implant, which should be cross-referenced at mrisafety.com to verify 3T compatibility, along with a signed medical implant clearance form (included at the end of this document) and is ultimately subject to written approval from the director of MRI safety, Dr. Alayar Kangarlu. Any questions about the safety of a medical device or implant of any kind that cannot be verified must be directed to Dr. Kangarlu at Alayar.Kangarlu@nyspi.columbia.edu - critical implants (pacemakers, aneurism clips, etc) will not be allowed into the magnet room under any circumstance)
- Any participant who has worked with metal (cutting, grinding, welding, machining, etc.) must have an orbital X-Ray accompanied by a written radiologist's clearance before being scanned.
- Subjects with Tattoos, especially those that have been applied within the last six months, and those near or on the face and neck, are subject to approval by the MRI Safety Director. *Please see attached flowchart
- Permanent retainers and most fillings are generally MRI safe, however the participant should be mindful to alert for any unusual sensations, and it is noted that the quality of certain images may be affected by dental work. Older fillings, jaw implants, etc., should be treated as standard surgical implants and are subject to the approval of the MRI Safety Director * Please see attached flowchart
- in order to ensure continued proper operation of the bed's hydraulic lift motor, the maximum subject weight limit for the scanner is 300lbs. The bore diameter is 70cm. Larger subjects whose measurements may cause them to exceed the inner dimensions of the bore may experience discomfort; excessive friction may create excessive resistance when entering the bore and could cause the bed to stop automatically for safety reasons, at which point the bed may not be forced.
- The physical confinement and isolation produced by the scanner could cause mild to moderate emotional distress. It is highly recommended that subjects who exhibit potential symptoms of anxiety or claustrophobia related to the scan be first allowed to experience the MRI simulator (mock scanner) to assess tolerance.
- Subjects being scanned under an IRB protocol for the first time or outside of six months of the subject's last scan, are required to have a structural brain image, if acquired, screened for incidental findings or "Safety Read," performed by a radiologist on behalf of the MRI research program, currently contracted through Imaging on Call. All radiological reports will be provided to groups within 30 days of the scan. Individual IRB protocols may mandate additional screenings.

At the time of the scan, the following should be given to the scanner operator:

- For female participants between the ages of 10-60, if not post-menopausal, a pregnancy screening with a verified negative result must be provided and signed by qualified research personnel.
- Signed participant consent form(s) for the study.
- A fully completed and signed metal screener.
- Any relevant information related to medical devices or implants (see above).
- Gadolinium consent with dosage, if applicable. Gadolinium procedures are outlined in a separate section entitled "Gadolinium Study Procedures."

Procedure for Participants with metallic Implants

Participants with dental filling do not require safety clearance. For participants with metallic implants, investigators must follow the procedure below and complete them at least 2 weeks before the scheduled scan as these implants may create problems during an MRI scan:

1. 1. Use the "Surgeon's Clearance Form" from this manual, and have the surgeon fill it out and sign and send the form back to Mr. Joe Figliolia.
2. 2. If the Surgeon has cleared the participant for a 3T MRI, you may proceed with the scan and stop here. Otherwise proceed to step 3.
3. 3. Contact MRI Safety Director, Dr. Alayar Kangarlu, by email and send all the information that you have about the implant to him. If he clears the participant, you may proceed with scanning and stop here. Otherwise proceed to step 4.
4. 4. Dr. Kangarlu might request specific supporting material such as composition, model and make of the implant that must be provided to him. Such information could be obtained from the manufacturer of the implant. If Dr. Kangarlu clears the participant based on this documentation, you may proceed with the scan and stop here. Otherwise, proceed to step 5.
5. 5. Schedule a meeting for the participant and a member of the study team with Dr. Kangarlu.
6. 6. If Dr Kangarlu's conversation with participant offers him enough information that he clears the participant, then you may proceed with the scan and stop here.

This process must be completed at least two weeks before the scheduled scan date. All clearances will be logged by Dr. Kangarlu and reported to the MRI operations committee.

After a participant is cleared, it is still important that he/she enters the MRI Scanner room very slowly to provide ample time to respond to any possible interaction with the magnetic field. Any friend or relative who accompanies the participant during the scan will likewise be instructed to remove all metallic objects and complete a metal screening form.

As stated in other sections of this manual, if you have questions or concerns about any health condition other than implanted devices that could impact the MRI procedure, you may contact Dr. Kangarlu to discuss any safety concerns that a participant might have, etc. This is particularly important if a participant has undergone surgery, involving the brain, ear, eye, heart, or blood vessels.

Before entering the magnet room:

- All Participants must be hand-screened in view of the scanner operator with the metal detection wand. Be sure to pass the wand carefully and slowly over the participant, nearly making contact.
- The participant must remove any of the following items before being scanned, without exception: Any jewelry (including facial/body piercings), belts, underwire bras, bobby pins and hair clips of any kind, dentures, temporary metallic tattoos, any athletic clothing that contains silver mesh, hearing aids, prosthetics, glasses, keys, loose change, credit cards, wallets, watches, items of clothing with excessive metallic embellishment (most pants zippers and rivets are ok) and anything the scanner operator deems otherwise unsafe at the time of the scan.
- If there are **any doubts** regarding the metal screening responses, do not allow the individual to enter the scanner room. The fact that the individual has been scanned in an MR scanner previously (even at the CUMC) is never a sufficient basis upon which to conclude that the subject can enter the scanner room safely, since risks vary according to magnetic field strength.

IN-ROOM PROCEDURES

- Participants will be given a sanitary head cover as well as acoustic dampening earplugs. Participants will not be scanned without appropriate ear/hearing protection. Participants should be informed prior to the scan session.
- Participants will be given padding to ensure comfortable positioning during the scan, as well as a blanket, should they desire.
- All participants will be given a "alert bulb" to hold during the scan session. If at any time the participant squeezes the bulb, the scanner will be stopped immediately to speak to the participant. If the participant wishes to be removed from the scanner, the operator will immediately remove the participant from the scanner. Investigators and RA's may speak to the participant to assess their desire to continue, but must do so outside of the scanning environment. Under no circumstances will a participant under distress be allowed to remain in the scanner. A scan session may be terminated at the operator's discretion should a participant exhibit signs of distress during a scan.
- All physiological monitoring cables and wires should be free from loops before connecting them to the participant.
- Participants should be properly insulated from contacting the inner surface of the bore with bare skin.
- Participants should be instructed to refrain from allowing their legs, feet, hands, arms, etc., to cross or overlap during the scan session.
- Should an adverse event occur during the scan session, the scan will be immediately terminated. It is the responsibility of the Study PI to report the event to the IRB as well as notify the MRI Safety Director and MRI Research Program Director.

GADOLINIUM STUDY PROCEDURES

- An MD will cover each scan (“covering MD”). The covering MD will be either an investigator on the protocol, or an MD provided by the MRI unit.
- The covering MD will be BLS certified and will be trained in the use of an epinephrine auto-injector (“epi pen”). An epi pen will be provided by the MRI unit and kept on the unit.

Advance Preparation

- The participant’s creatinine clearance will be determined by study research staff. For studies covered by the MRI unit, the participant’s weight and creatinine clearance and the study creatinine clearance inclusion criterion will be entered into the MRI unit gadolinium study form. The study staff will present the completed gadolinium study form to the covering MD. The covering MD will verify that the subject meets the creatinine clearance inclusion criterion and will exclude subjects who do not or for whom the completed gadolinium form is not presented.
- An IV catheter with t-connector will be placed by study research staff or the covering MD. IV supplies will be available if needed on the MRI unit.
- The participant’s weight will be measured and communicated to the covering MD and MRI technologist. The MRI technologist will use this information to determine the volume dose of gadolinium solution and verify the dose with the covering MD prior to preparing it.
- The MRI technologist will set up the gadolinium power injector with the appropriate IV line and gadolinium dose and will connect the injector, line, and t-connector attached to the participant’s iv catheter, keeping the components sterile.
- Pulse oximetry will be established.
- The covering MD/RN will confirm access to the epi pen.

Scan Coverage

- The covering MD/RN will be present at the time of gadolinium injection and will monitor the participant beginning at least 5 minutes prior to the time of injection until at least 10 minutes following injection via pulse oximetry.
- The covering MD/RN will remove the iv catheter following the end of the scan.

IN CASE OF EMERGENCY

- The covering MD/RN will administer epinephrine via epi pen if indicated and provide supportive care as indicated including CPR and oxygen until arrival of emergency response personnel.
- In case of an arrest the MRI unit staff will call
 - o the NYSPI rapid response team
 - o the NYPH code team
 - o 911
 - o the MRI unit director and medical director
- In case of an arrest MRI unit staff will assist response personnel with removing the patient from the MRI bed. An MRI safe mobile patient table is located in the magnet room next to the scanner and may be used for patient transport in an emergency.
- In case of resolution of the emergency (e.g. emesis in the scanner) the study may resume

INFECTION CONTROL PROCEDURES FOR HUMAN STUDIES

- Operators are to wash hands between all subjects.
- The MRI table will be covered with a sheet. Sheets will be changed after each subject.
- All contaminated products will be discarded in the red bags marked for waste.
- The sharps container will be removed if 3/ 4 full.
- The magnet room table and headrest will be wiped with a Sani-wipe at the end of the day.
- Any bodily fluids must be cleaned using standard infection control procedures. Any contaminated surfaces will be cleaned and treated with Virkon to prevent potential spread of infection.

MRI-SPECIFIC SAFETY RISKS

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

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

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.

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.

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.

SUMMARY OF EMERGENCY PROCEDURES FOR THE MRI UNIT

MEDICAL EMERGENCIES

1. Call x5555 and relay the location and nature of the emergency to the response team
2. Subject will be evaluated 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 assist with the removal of the subject immediately from the magnet room via the MR compatible transport stretcher and relocated 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 Director of MRI Safety will be notified immediately via a telephone and within 48 hours in writing.

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 MRI Safety Director will be notified immediately via a telephone call and within 48 hours of the incident in writing.

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

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 monitored remotely by GE. If any deviations from the expected pattern are noted, Dr. Kangarlu and Dr. Marsh 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.

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 cryogenics 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.

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.



PROCEDURE FOR POWER FAILURE

In the event of a power failure, the MRI console has a battery back-up (UPS) system that lasts for up to thirty minutes to permit an orderly shutdown of the console, and the magnet itself is protected by a DYSC power regulation system. If an MRI study is in progress, the patient will first be removed from the room by the MRI technologist. 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.

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



SAFETY PROCEDURES FOR MRI EXPERIMENTS INVOLVING ANIMALS

- 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.
- 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.
- The principal investigator will be responsible for making arrangements with the MRI administration for the use of the facility and the necessary technical expertise.
- 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.
- Animals will be transported to and within the MRI Unit in a way to minimize contact with patients and hospital staff.
- Prior to being transported to the MRI suite the primate will be kept NPO and anesthetized to ensure an uneventful delivery.
- 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.
- 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.
- 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-wipes and Virkon.
- All sheets, pads, or other material, such as syringes or I.V. tubing, etc will be disposed of in the "red bag" biohazard container.
- All of the surfaces that come into contact with the animal will be disinfected using Virkon.
- 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.

INCIDENT REPORTS

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

1. Incidents in which any person or animal 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 MRI Safety Director 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, and incidents involving animals should be reported to the IACUC within 24 hours.
- o The MRI safety Director 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, IACUC, 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.

NYSPI MRI Safety Committee (NMSC)

History

The NMSC was formed in 2004 and has been supervising MRI safety and safety of new technologies at the MRI Research Unit (MRIRU) at New York State Psychiatric Institute (NYSPI). The safety of research subjects, investigators, study personnel and equipment using standard or FDA approved technology is governed by the instruction in our Safety Manual. Considering that MRIRU was founded as a center to offer the latest MRI tools to Columbia and NYSPI scientists, it required a continuous development and acquisition of MRI techniques, both software and hardware, to keep our investigators equipped with competitive technology in their research. As such, in 2004, Alayar Kangarlu, PhD was hired as the Director of MRI Physics and Safety of the MRIUR to lead the MRI science and technology development and disseminate the knowledge of MRI Physics and training of our investigators for safe operation of MRI scanners at NYSPI. As the most rapid development in MRI occurs in software (pulse sequences) and hardware (RF coils), Dr Kangarlu formed the NMSC by inviting members of CUMC faculty and other institutions in NYC area with relevant expertise in those areas to serve in NMSC. The Committee has been comprised of 5 members who review new technologies developed in our RF Lab and Pulse Sequence Development Lab or acquired from other institution for implementation on human subjects.

Mission Statement

The mission of the MRI Safety Committee (NMSC) is to ensure that only safe MRI technology is offered to researchers at NYSPI. This mission is accomplished by a thorough review of any new technology that is developed in house or acquired from other institution to be used with human participant in studies using MRI. In addition, the Chair of NMSC provides the necessary safety training for researchers and staff, to make sure that only trained individuals have access to the scanner. Dr Kangarlu also evaluates the safe use of accessory equipment in scanner room and offers investigators and the staff with any safety insights that they might need for safe scanning of their subjects.

Committee Members

Members of the committee are invited by Dr Kangarlu to serve on NMSC for five years. The committee currently consists of individuals with clinical, basic science and MRI research experience to review new MRI technologies.

Chair: Alayar Kangarlu, PhD
Associate Professor of Neurobiology
Columbia University
Director of MRI Physics and Safety
New York State Psychiatric Institute
Phone: (646) 774-7256

Ernst Garcon, MD
Associate Professor of Neuroradiology
Department of Radiology
Columbia University
630 W 168th St, New York, NY 10032
Phone: (212) 305-2447

Co-Chair: Lawrence Kegeles, MD
Associate Professor of Clinical Psychiatry
Columbia University
Medical Director, MRI Research Program
New York State Psychiatric Institute
Phone: (646) 774-5560

David Guilfoyle, PhD
Research Scientist
Center for Biomedical Imaging and Neuromodulation
Nathan Kline Institute
845-398-5573

Marianne Garland, MD
Associate Professor of Pediatrics
Medical Director of the Neonatal Intensive Care Unit (NICU) Medical Director for the Physician Extender Program
New York-Presbyterian
3959 Broadway # 517, New York, NY 10032
Phone: (212) 305-5437

Craig Branch, PhD
Associate Professor, Department of Radiology, Physiology & Biophysics
Director, Gruss Magnetic Resonance Research Center, Department of Radiology
Albert Einstein College of Medicine
Phone: (718) 430-8917
Kevin Koch, PhD

New York State Psychiatric Institute – MRI Research Program

MRI Safety Metal Screening Questionnaire

SUBJECT ID (NO NAMES)	YEAR OF BIRTH	WEIGHT	DATE OF SCREENING
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The following items may make it **unsafe** for you to undergo MR imaging. Please indicate if you have any of the following by checking Yes or No:

- | | |
|---|--|
| <input type="checkbox"/> Yes <input type="checkbox"/> No Aneurysm clip(s) | <input type="checkbox"/> Yes <input type="checkbox"/> No Vascular access |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Cardiac pacemaker | <input type="checkbox"/> Yes <input type="checkbox"/> No Radiation seeds or implants |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Implanted defibrillator | <input type="checkbox"/> Yes <input type="checkbox"/> No Thermodilution catheter |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Electronic implant or device | <input type="checkbox"/> Yes <input type="checkbox"/> No Medication patch |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Magnetically-activated implant | <input type="checkbox"/> Yes <input type="checkbox"/> No Shunt (spinal or intraventricular) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Neurostimulation system | <input type="checkbox"/> Yes <input type="checkbox"/> No metallic fragment or foreign body |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Spinal cord stimulator | <input type="checkbox"/> Yes <input type="checkbox"/> No Wire mesh implant |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Internal electrodes or wires | <input type="checkbox"/> Yes <input type="checkbox"/> No Tissue expander (e.g., breast) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Bone growth/bone stimulator | <input type="checkbox"/> Yes <input type="checkbox"/> No Surgical staples, clips, or sutures |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Cochlear or other ear implant | <input type="checkbox"/> Yes <input type="checkbox"/> No Joint replacement (hip, knee, etc) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Insulin or other infusion pump | <input type="checkbox"/> Yes <input type="checkbox"/> No Bone/joint pin, screw, wire, plate |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Implanted drug infusion device | <input type="checkbox"/> Yes <input type="checkbox"/> No IUD, diaphragm, or pessary |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Any type of prosthesis (eye, etc.) | <input type="checkbox"/> Yes <input type="checkbox"/> No Dentures or partial plates |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Heart valve prosthesis | <input type="checkbox"/> Yes <input type="checkbox"/> No Tattoo or permanent makeup |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Eyelid spring or wire | <input type="checkbox"/> Yes <input type="checkbox"/> No Body piercing jewelry |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Artificial or prosthetic limb | <input type="checkbox"/> Yes <input type="checkbox"/> No Hearing aid |
| <input type="checkbox"/> Yes <input type="checkbox"/> No Metallic stent, filter, or coil | <input type="checkbox"/> Yes <input type="checkbox"/> No Other implant _____ |

Please verify if any of the following are applicable:

- Are you presently working, or have you ever worked as a machinist, metal worker, or in any profession grinding or using (e.g. artistically) metal? Yes No
- Any injury to the eye involving a metallic object or fragment (shrapnel, metal filings, etc.) Yes No
- Any bodily injury by a metallic object or foreign body (shrapnel, metal filings, bullet, etc.) Yes No
- Breathing problems or motion disorders Yes No
- Claustrophobia or discomfort in confined spaces Yes No
- Are you currently pregnant? If no, please provide date of LMP ___/___/___ N/A Yes No

IMPORTANT

Before entering the MR environment or MR system room, you must remove all metallic objects including: hearing aids, dentures, partial plates, keys, cell phones, eyeglasses, hair pins, barrettes, ALL jewelry, body piercings, watches, safet pins, paperclips, money clips, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knives, nail clippers, tools, & clothing with metallic threads.

Subject has been screened with handheld metal detector Yes No

If Metal was detected, please indicate action taken: _____

If applicable, MRI compatible medical Implant clearance provided: N/A Yes No

By signing below, I attest that the above information is correct to the best of my knowledge. I have read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

PARTICIPANT SIGNATURE _____ DATE ___/___/___

RESEARCH PERSONNEL _____ DATE ___/___/___

MRI TECHNOLOGIST _____ DATE ___/___/___



**New York State
Psychiatric Institute**

APP. DATE: _____

Name: _____
 Sex: M F
 Date of birth: _____
 Address: _____
 City: _____ Province: _____ Postal code: _____
 Parent / guardian: _____
 Telephone: _____
 Registration # _____

Request for Proof of MRI-Safe Implants

This Form is intended to be filled out by the implanting surgeon as an indication that it is safe for the patient named on this form to be scanned in a 3T MRI scanner.

1. Will the patient feel any discomfort at the site of implant?
 Yes No

Patient weight _____ kg Height _____ cm Age: _____

2. Has this person been scanned before Prior to Implant After Implant
 (please specify the details of each scan)

3. Briefly explain the device that has been implanted in this patient. (anatomical site, symptoms, clinical findings)

4. Additional relevant history and comments (previous reaction to contrast, allergies, isolation, cardiac anomaly, special positioning, etc.)

5. Preferred date of exam:

Reasons for the preferred date:

6. Principal Investigator

First name: _____ Last name: _____ Department: _____

Address: _____ Fax #: _____

Contact numbers: 1. _____ 2. _____

7. Principal Investigator's Signature: _____ Print name: _____

Please print NYSPI STAFF Requesting the Proof name: _____ Date: _____ Time: _____

Incomplete, illegible or inaccurate forms will be returned to you, resulting in a delay in obtaining an appointment.

MRI Waiver

MRI Suite
New York State Psychiatric Institute
Dept. of Psychiatry

RE: _____ Tattoo

To whom it may concern:

According to the NYSPI policy, you need to sign this official letter of waiver prior to undergoing MRI scan.

I, _____, do hereby agree to undergo an MRI Scan knowing there may be a risk of heating, burns and/or permanent scarring on or around the area of the tattoo/makeup tattoo.

I acknowledge and accept this risk and agree to proceed with the MRI scan.

Participant's Signature: _____ Printed Name: _____

Date: _____

Coordinator's Signature: _____ Printed Name: _____

Date: _____

Exencion de MRI

MRI Suite
New York State Psychiatric Institute
Dept. of Psychiatry

RE: Maquillaje tatuado

De acuerdo con la política del NYSPI, debe firmar esta carta oficial de exención antes de someterse a una exploración de resonancia magnética (MRI).

Yo, _____, estoy de acuerdo en someterme a una exploración de resonancia magnética (MRI) sabiendo que puede haber un riesgo de calentamiento, quemaduras y / o cicatrices permanentes en el área del tatuaje / maquillaje.

Reconozco y acepto este riesgo y acepto proceder con la exploración de MRI.

Firma del Participante: _____ Nombre impreso: _____

Fecha: _____

Firma del Coordinador: _____ Nombre impreso: _____

Fecha: _____

