



THE NYSPI MRI RESEARCH PROGRAM

SAFETY POLICIES & PROCEDURES

SAFETY POLICIES AND PROCEDURES MANUAL
MAGNETIC RESONANCE IMAGING UNIT
NEW YORK STATE PSYCHIATRIC INSTITUTE

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For Questions regarding the safety of surgical implants or other medical devices, please email Gaurav Patel and Matthew Riddle. For questions regarding the safety of monitoring equipment, peripherals, or other devices to be used in conjunction with MRI scans, please email Yunsuo Duan and Gaurav Patel.

The most up-to-date version of this manual can be found at <https://www.nyspi.org>

STARTING A SCAN PROTOCOL AT NYSPI

BEFORE GRANT APPLICATION

COMPLETE THE MRI APPROVAL FOR GRANT APPLICATIONS

This form allows us to evaluate feasibility scheduling availability, and the opportunity to provide guidance to help ensure a successful outcome. A copy of this form, once signed, will be automatically emailed to the division administrator

BEFORE IRB APPROVAL

OBTAIN MRI DIRECTOR PROTOCOL APPROVAL

This allows for review to ensure the proposed protocol follows the guidelines set forth in the MRI Safety Manual, including approval of any devices, sequences and of any procedures involving minors. After completion of REDCap form and subsequent protocol review, a signed approval letter will be provided for the relevant IRB.

AFTER IRB APPROVAL

COMPLETE THE PROJECT INITIATION FORM

This form collects the necessary information to allow initiation of the scan protocol and to set up data processing. After completion, a protocol will be built in the console, and the project added to XNAT and the scheduling system.

THE NYSPI SCANNING SUITE



ZONE 1

Participants, research team members, other facility staff, and visitors may enter zone 1. Research staff and other visitors are limited to zone 1 before completing MR Safety training unless otherwise approved by an MRI Safety Officer. Zone 3 is considered safe for general access during the MRI Unit's operating hours.

ZONE 2

Zone 2 is the area immediately outside of the Magnet Room, which contains the MR Console as well as the experiment equipment interfaces. Untrained research staff, approved visitors, and facility staff are limited to Zone 2. Participants should not enter Zone 2 until the MR Operator has acknowledged receipt and review of all safety screening materials. Staff, faculty and other visitors may not enter Zone 2 if they have any conditions, implants, or otherwise that would be unsafe when subjected to a strong magnetic field or RF Interference.

ZONE 3

Zone 3 is the magnet room itself, as well as the animal prep room. Research faculty and staff who have been granted final safety approval and MR Personnel may enter Zone 3. Participants should not enter zone 3 unless escorted by MR Personnel. Anyone entering Zone is subject to the same safety screening criteria as someone undergoing an MR scan.

CONTROL ROOM

The control room contains high voltage power electrical equipment, as well as MR and related cooling equipment, and the physiology amplifiers. Access to the control room is limited to Facility staff for the purposes of maintenance and repair, as well as MR Personnel. Research team members should not enter the control room at any time unless directed by MR Personnel.

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 subjects and animal 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 required. 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 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 certain contracts and animal scans, which fall under supervision of the IACUC.

*Currently, human subject research at NYSPI falls under the jurisdiction of Advarra and NKI IRBs.

OPERATORS OF THE MRI SCANNER

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

Be an employee of the NYSPI MRI Research Program or have otherwise demonstrated competency and given special approval by a director of the MRI Research Program

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

Have successfully completed the NYSPI MRI Safety Training

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

If a licensed MRI Technologist*, the operator will have completed a formal class on Radiological procedures, will have current license by the American Registry of Radiological Technologists.

*a licensed technologist is not required for non-clinical research scans

TRAINING AND ACCESS

Only MRI Faculty and Staff, and research Faculty and Staff who have successfully completed NYSPI MRI Safety training, as well as required shadowing, will be granted ID card access to the MRI Suite during normal working hours.

After successful completion of the NYSPI MRI safety training, faculty and staff must attend three scan sessions and demonstrate self-sufficiency before being allowed to run scans without other members of their research group present. It is recommended that these scan sessions contain procedures relevant to their own scan protocols.

Faculty and Staff may enter the magnet room during shadowing sessions but ONLY with another fully-trained staff or faculty member, or member of the MRI Unit staff.

A Database of attendance, passing, and current approval status for each staff and faculty member will be maintained by the MRI Unit., accessible to the Directors and Unit Administrator.

All participants and their families and companions must remain in the family waiting and/or prep areas at all times unless escorted by fully trained faculty or staff. Under no circumstances should a participant be allowed to enter the magnet room without first being formally screened. Participants must be verified to be free of ALL ferrous metals or other potentially dangerous objects before entering the magnet room.

Food and drink are allowed in the console and waiting areas, but are NOT allowed in the magnet room under any circumstances, including water.

EQUIPMENT AND SAFETY LABELING

All equipment, instruments and devices should be clearly labeled to indicate their safety status in the MR Environment. There are typically three types of safety indications: MR Safe, MR Conditional and MR Unsafe.



MR SAFE



MR CONDITIONAL



MR UNSAFE

MR Safe: an item that poses no known hazards in the MR Environment. MR safe can only be applied to objects that are 100% safe to be taken, used or placed within the MR Environment without any risk of potential harm. MR Safe items include non-conducting, non-metallic and nonmagnetic items.

MR Conditional: an item that has been demonstrated to pose no known hazards in a specified MR Environment with specified conditions of use. Field conditions that define the specific MR Environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), RF fields and SAR. For MR Conditional items, the item labeling or provided information will include results of testing sufficient to characterize the behavior of the item in the MR Environment. In particular, testing for items that may be placed in the MR Environment should address magnetically induced displacement force and torque and RF heating. Other possible safety issues include thermal injury, induced currents/voltages, electromagnetic compatibility, neurostimulation, acoustic noise, interaction among devices, the safe functioning of the item and the safe operation of the MR system. An item with this label warns the user that there are limitations to the usability or to the testing that was performed on it. In other words, the item may have been tested for a 1.5 T system, but not for a 3 T system. Any parameter that affects the safety of the item should be listed and any condition that is known to produce an unsafe condition must be described on the item, in its packaging or in its accompanying instructions.

MR Conditional items should not be stored in the MR Environment and should be brought into the MR Environment only by MRI Operators or fully training scanning staff and faculty who are cognizant of the operating conditions and can confirm that such items' restrictions are compatible with those conditions.

MR Unsafe: an object that poses a known threat or hazard in the MR Environment. MR Unsafe items are prohibited from Zones III and IV. All equipment in the MR Facilities must be labeled for suitability for the MR Environment. Unmarked objects should be assumed to be MR Unsafe unless they are clearly non-metallic throughout. MR Unsafe items include magnetic materials. UNDER NO CONDITIONS SHOULD AN MRI UNSAFE MATERIAL BE BROUGHT INTO THE MAGNET ROOM

TATTOOS

Guidance for tattoos is provided automatically by the MRI Screening Form based on the following guidelines:

- Tattoos over six months old are generally considered safe for the MRI environment and do not require further review unless the subject has an unusual amount of coverage (i.e., full blackout skin sections, etc)
- Tattoos under six months old and located above the neckline are not allowed and are considered unsafe for our scanner
- Tattoos under six months old and located below the neckline are subject to approval. Groups must provide the following information a minimum of one week in advance of the scan session for review: The location of the tattoo, the colors and brands of the ink used, and the size of the tattoo.

If approval is granted, said approval must be attached in PDF form to the participant's MRI Screening Form before submission.

SURGICAL IMPLANTS AND MEDICAL DEVICES

Guidance for all implants and medical devices is provided on the MRI Screening Form. Based on participant responses, the form will indicate whether or not a device is allowed, or requires review. Certain devices, while allowed in clinical scans, are not allowed in our MRI environment due to the level of risk involved. These include pacemakers, aneurysm clips, and other cardiac stimulation devices, as well as devices that provide electronic or magnetic stimulation. If the MRI Screening form indicates that a device requires review, groups must provide the following information to both the MRI Medical Director and MRI Operations Director a minimum of two weeks before the scan session, at which point the workflow for approval will commence (see page 27)

- The type of implant, and location
- The manufacturer's information, including specific model. If this is unknown, please provide as much information as possible, preferably from the implanting surgeon or hospital.

If approval is granted, said approval must be attached in PDF form to the participant's MRI Screening Form before submission.

IUDS & BIRTH CONTROL IMPLANTS

All current IUDs and sub-dermal birth control implants, if implanted in the United States by a licensed provider, are considered safe for our MRI. It is recommend that participants with Copper IUDs have them examined for migration post scan.

NEW DEVICES USED WITHIN THE MR ENVIRONMENT DURING SCANS

If a group plans to use a peripheral, monitoring device, or other equipment during their scan sessions that has not been previously approved for use in the NYSPI scanner, they must get prior approval before use. The following should be provided via email to Yunsuo Duan at least two weeks before using or testing the device in the MR environment:

- The type of equipment or device
- The manufacturer, as well as all manuals or relevant materials stating its safety in an MR environment, or otherwise a complete list of all materials used in its construction.

Dr. Duan will review the materials and make a determination as to the safety of the device and, if determined to be safe for our MRI, provide official approval to proceed.

SUMMARY OF PARTICIPANT AND RESEARCH TEAM PROCEDURES FOR SCAN SESSIONS

Before a scheduled scan date and as soon as possible after signing consent, we recommend that the study team administer the REDCap MRI Unit Screener to assess MRI safety for the participant. The MRI Unit has made available a modified version of the MRI Unit Screening form to allow groups to assist in pre-screening participants.

A 'yes' response to any item on the MRI Unit Screener will spark immediate branching logic that will provide guidance with regard to participant safety, including consultation with an MRI Safety Officer. Consultation may lead to a request for further documentation (e.g., surgeon's documentation for implants; type of tattoo ink). Consultation procedures followed by the MRI safety team in cases of implanted devices are documented below in the section on the Joint MR Research Safety Committee.

The MRI Unit Screener must be updated within 24 hours before each scheduled scan. The study team member who administers the form will document who was present (which should include the study team member, the participant, and if a minor, a parent or legal guardian) during completion of the form and sign it, as well as attach copies of the participant's signed consent, and any relevant email approval or documentation before submitting the REDCap survey to the MRI Unit. A pregnancy test verification form must also be completed in REDCap if applicable. The finalized screening form should be submitted at least two hours before the scan session to allow time for review.

An MRI operator will provide final approval and review of the REDCap form before scanning.

If a participant provides new information in the 24-hour update of any contraindication listed on the MRI Unit Screener that was not previously documented and approved, the scan cannot proceed. This includes last minute disclosure of implants, tattoos, or other non-removable items that may indicate the need for review or present a clear risk for the participant in the scanner environment.

A link to the updated and signed REDCap MRI Unit Screener will be automatically emailed to MRI operators, but this along with other documentation may be requested by an MRI safety officer for additional review if needed.

PARTICIPANT COMFORT

To ensure continued proper operation of the bed's hydraulic motor, the maximum participant weight limit for the scanner is 300lbs. The bore diameter is 70cm. Larger participants 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 participants who exhibit potential symptoms of anxiety related to the scan be first allowed to experience the MRI simulator (mock scanner) to assess tolerance.

Participants being scanned under an IRB protocol for the first time or outside of six months of the participant's last scan, are required to have a structural brain image screened for incidental findings or a "Safety Read," performed by a radiologist on behalf of the MRI research program, currently contracted through a teleradiology service. All radiological reports will be provided to groups within 30 days of the scan. Guidance for investigators on these procedures is provided below in the APPENDIX: IRB GUIDELINES FOR MRI USERS.

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, in view of the scanner operator.
- The participant must remove any of the following items before being scanned, without exception: Any metal jewelry (including facial/body piercings), belts, underwire bras, bobby pins and hair clips of any kind, wigs, dentures, partial plates, temporary metallic tattoos, tools, any athletic clothing that contains silver mesh, hearing aids, prosthetics, glasses, keys, knives, loose change/ coins, credit cards, magnetic stripe cards, phones, wallets, watches, paperclips, money clips, 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 MRI Unit Screener 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 CUMC or ZMBBI) is never a sufficient basis upon which to conclude that the participant can enter the scanner room safely, since risks vary according to magnetic field strength

FAILURE TO ADHERE TO THESE GUIDELINES CAN LEAD TO SERIOUS INJURY OR DEATH

SPECIAL CONSIDERATIONS FOR MRI WITH MINORS

- All procedures for MRI with minors (individuals under 18 years of age) must be approved by an MRI Director and the appropriate IRB.
- Minors must be accompanied by an adult to the MRI unit.
- A parent/legal guardian must be present during the initial MRI Unit Screener review (in person, virtually, or by phone) and update. The minor may be given an opportunity separately from the parent/legal guardian to provide information that they did not feel comfortable revealing in front of their parent/guardian.

Neonates and Infants

- Axillary temperatures of the infant should be recorded before and after the scan to ensure temperature stability.
- Either the presence of a clinician (MD or nurse practitioner) or research staff trained in infant resuscitation and basic CPR should be present to observe and monitor infant during duration of MRI procedure.
- A pulse oximeter is available in the MRI unit to monitor heart rate and oxygen saturation when necessary.

IN-ROOM SAFETY PROCEDURES

- Participants will be given an optional sanitary head cover as well as acoustic dampening earplugs. Participants will not be scanned without appropriate ear/hearing protection. Participants should be informed of this requirement 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 extreme 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 scanner 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 an MRI Safety Officer and an MRI Research Program Director.

INFECTION CONTROL PROCEDURES FOR HUMAN STUDIES

- Operators are to wash hands between all subjects. They may optionally wear gloves
- 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, Radio-frequency (RF) Magnetic Fields, and Static Magnetic Fields.

Acoustic Noise

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 the use of disposable acousting-damping earplugs or ear covers.

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

The main risk of RF fields is burns. Skin contact against RF transmission and receive coils and cables can result in direct burns. Coils and cables are typically insulated and sealed within a thick plastic protective sleeve to provide a minimum safe distance. Clothing or non-conductive pads can provide protection.

More common are burns from electromagnetic induction, where generated current from changing magnetic fields produces an excessive amount of heat. Gradient or RF coils provide the source of the fluctuating magnetic fields, but the current can be produced within any conducting material, either internal or external to the body. Precaution should be taken to prevent local thermogenic pain, damage or systemic stress during the scanning as follows:

- Avoid skin-to-skin contact; the subject's hands should not be placed on his/her hips and the subject's arms should not be crossed. The subject should be instructed to refrain from allowing their legs, feet, hands, arms, etc. to cross or overlap during the scanning. A spacer should be placed between the feet so that the toes and calves are not touching when restricting movement of legs for pelvic imaging.
- Use padding to separate a subject's limbs and body from the magnet bore, and their legs from their torso. There should be no body loops formed through adjacent tissue contact with arms or legs.
- Route cables in a straight line. Do not coil cables or allow them to touch the subject.
- Ensure that no body part is in direct contact with the bore. A minimum distance (typically 5 mm, but dependent upon specific scanner model) is required between the bore and the subject.
- Cold packs should be available for application to areas of concern to prevent heating.
- Use the lowest possible SAR values in the scanning.
- Maintain two-way communication between the MR operator and the subject throughout the scanning.

MRI scanning induces some heating of body tissues. This specific absorption rate (SAR) that determines heating is the amount of radio-frequency (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 < 4.0 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 radio-frequency 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." (continued on next page)

It should be noted that this guideline is based on the calculation of a system that has no thermo-regulatory 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 $\pm 1^{\circ}\text{C}$ from the normal set point 37°C , and healthy people with normal thermo-regulatory 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.

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 FDA has deemed that systems operating at 8.0 Tesla or less do not pose a significant risk. 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.

This category of risk applies to work conducted around superconducting magnets of any kind (including standard clinical diagnostic MRI units). 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 non-significant 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 Operator 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 the MRI and MRI Medical director will be notified immediately via a telephone and within 48 hours 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

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

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. 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. Patel and Dr. Marsh will be notified immediately and adequate measures will be 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 participant 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 participant 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 participant.
4. The participant 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 Operator, 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 magnet itself is protected by a DYSC power regulation system to prevent surges in the event of a blackout or brownout event. If an MRI study is in progress, the participant will first be removed from the room by the MRI operator. Once participant safety is secured, the MRI operator will return to the MRI suite and turn off all of the computers running on battery backup. 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 Operator, 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 operator should:

1. Use the intercom to alert the participant to stay calm and remain on the table until the operator 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 participant 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 NYP-CUIMC 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 a Director of the MRI 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 Director of the MRI.

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.

It is required to report these various categories of incidents within the following time periods:

- Incidents 1 and 2 above: To the Joint MR Safety Committee, the MRI Unit Director, and the Environment of Care Committee immediately
- Incidents 3 and 4 above: To the Joint MR Safety Committee, the MRI Unit Director, and the Environment of Care Committee within 24 hours.
- Incident 5 above: To the Joint MR 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.
- The Director of the MRI 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 responsibility 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.

JOINT MR RESEARCH SAFETY COMMITTEE

The Joint MR Research Safety Committee (JMRSC) has been established under the MR Research Safety Program at CUIMC to be responsible for safety matters in the MR Facilities. The JMRSC is comprised of individuals from each of the Program Instructions who are knowledgeable about MR equipment, MR experimental procedures, MR research and the physics involved in MR scanning of human beings and animals. The members and Chair are appointed jointly by the Executive Vice President for Research of the University, the Executive Vice President and Dean of the Faculties of Health Sciences and Medicine of the University, the President and Chief Executive Officer of NYPH, and the Director of NYSPI, or in each case a designee. The JMRSC will perform, at a minimum, the following safety related tasks:

- Review the MR safety policies and this Manual periodically and revise the same as needed;
- Convene as needed, but no less than once per year;
- Approve the use of implants and devices (a) that are unlabeled, (b) that are labeled MR Conditional, but are subject to novel or non-standard scanning conditions that fall outside of the strict conditions listed for the implant or device or (c) as to which there is current uncertainty as to their safety (Uncertain MR Devices);
- Review reports of MR Research Safety Issues (as defined in Section XI(A)) on a quarterly basis or as needed; and
- In the event that a MR Research Safety Issue occurs, oversee the implementation of a corrective and preventive action plan if needed. The JMRSC and Subcommittees referred to below will be governed by and operate pursuant to written By-Laws.

Current JMRSC Members as of July 2025

Dr. Marc Brown, Associate Professor of Radiology, CUIMC Department of Radiology

Dr. Peter F. Caracappa Executive Director, Chief Radiation Safety Officer, Environmental Health & Safety

Dr. Yunsuo Duan, Assistant Professor of Clinical Neurobiology, CUMC Department of Psychiatry

Dr. Raphael Gerraty, Managing Director, MRI Platform, Zuckerman Institute

Dr. Sachin Jambawalikar, Assistant Professor of Radiology, CUIMC Department of Radiology

Dr. Itamar Kahn, Associate Professor of Neuroscience, Jerome L. Greene Science Center

Dr. Rachel Marsh, Chair, Joint MR Research Safety Committee, Professor of Medical Psychology, CUIMC New York State Psychiatric Institute

Ms. Ran (Angela) Meng, Associate Director, Research Radiation Safety Program, Environmental Health & Safety

Benjamin Navot Assistant Professor of Radiology at CUIMC Department of Radiology

Dr. John Thomas Vaughn, Jr. Professor of Biomedical Engineering and Radiology, Jerome L. Greene Science Center

Committee procedures for evaluating implanted devices and materials:

If a 'yes' response on the MRI Unit Screener indicates in implanted material or device, the MRI operator or safety officer will request written documentation as to the type of device, implant or foreign object that might be present. Once positive identification has been made as to the type of device, implant or foreign object, best effort assessments will be made to identify the MR compatibility of the device, implant or object. A prior MR scan is not sufficient to clear a subject for an MR scan without verifying the device or implant. The decision procedures that will be followed are

- If the MR Safety Officer can make a confident decision (positive or negative) using the subject's information and <https://www.mrisafety.com> or other resources, the decision will be communicated to the study PI.
- If not, the MR Safety Officer will communicate to the study PI that there is a possible contraindication, and ask for confirmation from the PI the request to pursue scanning of the subject
- If the PI confirms the request to scan the subject, the scan and subject information will be referred to the Device and Implant Safety (DIS) Subcommittee of the Joint MR Research Safety Committee (JMRSC) of Columbia University.
- The DIS Subcommittee will consider the case and may make a consensus decision regarding the approval to scan the subject.

If the Subcommittee cannot reach consensus, or if the Subcommittee makes a negative determination and the PI chooses to appeal the decision of the Subcommittee, the case will be referred to the JMRSC.

APPENDIX: IRB GUIDELINES FOR MRI USERS

Level of Risk

In general, a non-invasive MRI procedure is considered to be “minimal risk” according to federal definitions. However, MRI studies in vulnerable populations, repeated MRI scanning procedures, MRIs requiring contrast or sedation, and MRI done in conjunction with other research interventions may not qualify as minimal risk or for expedited review.

Minimizing Risk

Each proposal must minimize risks and discomforts to participants, including:

Screening for metallic devices, implants, and other contraindications to scanning:

The MRI Unit Screener is part of the approval process to proceed with an MRI scan. See section above on P. 10, “SUMMARY OF PARTICIPANT AND RESEARCH TEAM PROCEDURES FOR MRI” for details on this requirement.

The Exclusion Criteria table should include the following language:

Exclusion: “Any condition or material in the body that is a contraindication for MRI procedures”

Method of Ascertainment: “Interview*”

* The MRI Unit Screener must also be completed and approved prior to scanning”

Exclusion: “Pregnancy of participant”

Method of Ascertainment: “Interview*”

* Negative urine pregnancy test is also required on the day of scan for participants with child-bearing potential”

While participants should be excluded who are unlikely to tolerate the confined space of the MRI scanner, this consideration will be addressed under the MRI Unit Screener and need not be listed as an additional exclusion criterion.

Additional considerations in minimizing risk:

- a) Providing adequate medical, safety monitoring and observation during scanning, as appropriate.
- b) Reducing scanning time to that necessary to accomplish the scientific aims of the study.
- c) Enhancing the subject’s physical and emotional comfort during the scan.

Approval For the Use of the NYSPI MRI Unit

Investigators are required to obtain written approval from the NYSPI MRI Director to use the 3 Tesla magnet. A copy of this approval must be submitted to the IRB as a condition of final protocol approval.

Description of MRI protocols

When describing an MRI protocol in an IRB PSF, provide a general description of the pulse sequences being used (e.g., structural, functional, neurochemical MRI). Detailed changes within a sequence over the course of the protocol need not lead to changes to the PSF given that the technology is periodically updated. However, a PSF should be updated if additional sequences are added to a protocol or if anything changes the amount of time in the scanner that was originally approved.

Clinical Readings of Research MRIs

Participants being scanned under an IRB protocol for the first time or outside of six months of the participant's last scan, are required to have a structural brain image (T1-weighted MRI) screened for incidental findings or a "Safety Read," performed by a radiologist on behalf of the MRI research program, currently contracted through a teleradiology service. All radiological reports will be provided to groups within 30 days of the scan. Individual IRB protocols may mandate additional screenings.

Timing of Interpretation and Communication of results:

- 1) Should an MRI technician or other member of the research team suspect that an MRI scan suggests evidence of a significant lesion, the PI of the study and teleradiology service is notified immediately to expedite the safety read.
- 2) The teleradiologist provides written reports to the investigator within one month of image acquisition.
- 3) All results should be shared with research subjects in a manner that is consistent with the acuity and certainty of the finding and should be communicated by an appropriately qualified member of the research team.
- 4) The PSF must detail all procedures for communication results and incidental findings to subjects as per this policy, and the consent form must indicate that the scan will be read, that irregular findings will be made available, and a statement about the clinical value or limitations of the reading.

Confidentiality

The PSF confidentiality section should describe where scans, associated clinical and identifying data, and clinical readings will be stored and how confidentiality will be maintained. If results are to be maintained on a widely available database, this information should be noted and described in the consent form

Consent

Consent must be discussed and documented by a qualified member of the research team. The individual must certify that he or she has completed human subjects training and has been trained in discussing consent. He or she must be supervised, as needed, during the consent procedure.

Sample Consent Form Language (please adapt as necessary for specific studies):

1. Alternatives to participation (same for all MRIs)

“This is not a treatment study. Information being collected is for research purposes only and is to learn more about _____, not about you. It is not necessary to participate in this research study to have an MRI, and the MRI done as part of this study is not the same as one done for medical purposes.

2. Study Procedures (same for all MRIs)

“MRI (Magnetic Resonance Imaging). The MRI uses strong magnetic fields and radio waves to take pictures of your brain. MRI involves lying on a table that slides into a large magnet shaped like a cylinder. Before beginning the imaging procedure, we will determine that you do not have a pacemaker or any unsafe metallic implants such as an aneurysm clip or heart valve and certain tattoos, and you will be asked to remove any metal or magnetized objects (such as keys, chains, jewelry, retainers, medication patches, hairpins or credit cards). You will be asked to lie flat on your back in the MRI scanner for minutes and to remain as still as possible. You will not feel anything, but you will hear a knocking, noise. This is a normal sound produced by the MRI scanner and does not indicate that anything is wrong.”

3. Study Risks

Study risks must be described in relation to the 3T Magnet. The full discussion of these risks provided above in Section 10, “MRI-SPECIFIC SAFETY RISKS” on P. 16 is more extensive than needed for the Consent Form. The following wording will be sufficient for typical protocols using MRI scanning: “For your MRI scan, we will run the scanner at a level called ‘First Controlled Operating level.’ With this level, all scans remain within the FDA’s safe operational limits and as a result, the FDA considers this mode of operation for our scanner to be non-significant risk.” (continued on next page)

“While there have been no reports of any harmful long-term effects caused by 3T magnets or magnets of even higher strength, the long-term effects of being placed in a magnet of this strength are unknown. Also, although there are no known risks associated with pregnancy, we will not scan someone who is pregnant. If you are a female in your child-bearing years, you will be asked to take a urine pregnancy test on the day of your scan to ensure that you are not pregnant.

Some people have reported sensations during MRI scans with the 3T magnet, such as “tingling” or “twitching” (or, very rarely, a painful sensation), which are caused by changes in the magnetic field that can stimulate nerves in your body. With any MRI scan, on occasion, some people experience nervousness or discomfort due to the scanner’s small space and the need to lie still.

Except for pacemakers, some types of metallic implants, medication patches, and possible tissue heating, we are not aware of any other potentially dangerous interactions or hazards associated with the MRI scan. The MRI scanner also produces a loud noise; ear-plugs will be provided to reduce this discomfort. If you experience any discomfort and wish to stop the scan, you can tell the MRI technologist, and he or she will stop the scan immediately. In our experience, no one has had sensations from the MRI that did not stop when the scanning stopped. The MRI scan is not painful, but lying still on the scanning table may be slightly “uncomfortable.”

4. Benefits regarding MRI:

“You are not expected to benefit from participation in this study.”

5. Results of your MRI:

“While MRI scans are sometimes done for clinical purposes, the kind of MRI scan you will have as part of this study is for research purposes only. This means that the scans are not designed to provide clinical information that might be helpful to you or your doctor and they may not show problems that would normally be found in an MRI ordered to evaluate a specific medical problem. It is likely that the MRI scan will not have the quality of those done for clinical purposes.” Then: “However, within a month of the MRI, the structural scan will be read by a neuroradiologist for evidence of any obvious irregularity requiring your follow-up. You, or a physician whom you may designate, will be informed only if there is an irregularity that may need clinical follow-up by your doctor. Given the nature of the scan, the absence of a finding does not mean that one is not present.

6. Confidentiality (re MRI):

“The results of your neuroradiological safety read will only be shared with the research team who will notify you of any potential irregularity.”

Guidelines for Informing Subjects

Subjects should be informed by a letter (the template must be approved by the NYS-PI-IRB) when there is evidence of a mass lesion, hydrocephalus or other significant abnormality. A qualified clinician should call the subject and then a letter should be sent, depending on the urgency, and at the discretion of the investigator and radiologist.

Sample language for informing subjects about neuroradiological findings

“As we mentioned in our recent telephone conversation, the review of your scan by a doctor trained in brain MRI interpretation (a neuroradiologist) showed an irregularity, and we recommend that you follow up with your physician as soon as possible to determine if any further action is necessary. Please let us know if you would like to request that a copy of the report be sent to your physician.”