

# **Polices and Procedures Manual**

## **BROWN UNIVERSITY MRI RESEARCH FACILITY**

**Brain Science Program**

**Sidney Frank Hall for Life Sciences**

**Prepared by MRF Staff and Associates**

**Approved by Brown University**

**11/21/2006**

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## SECTION 1: RESEARCH PROTOCOL REQUIREMENTS

This section establishes a set of criteria that Brown-affiliated Principal Investigators must satisfy prior to conducting research activities using the MRF resources. The MRF policies described below do not supercede established University polices and procedures developed by the IRB and IACUC.

### Definitions:

**PRINCIPAL INVESTIGATOR (PI):** Brown University affiliated scientist or clinician with faculty rank of Investigator or above. Post-doctoral fellows, medical fellows, graduate students, undergraduate students and staff cannot serve as a PI for an MRF project.

**RESEARCH PROTOCOL:** Set of documents related to the conduct of an experiment with humans, experimental animals, or materials.

Prospective researchers must submit application paperwork to the MRF for approval in addition to obtaining approval from the IRB or IACUC, as appropriate. All paperwork being submitted to the MRF should be submitted in electronic form (preferably in PDF format) to:

MRIResearch@Brown.edu

A hard copy of any forms requiring an original signature should be sent to:

MRF  
Department of Neuroscience  
185 Meeting Street  
Brown University  
Providence, RI 02912

The application and approval process is as follows:

1. **MRF Application Form:** A completed application form (Exhibit A) must be submitted and approved by the MRF for each research project. An unsigned face-page or one with an electronic signature should be submitted via E-mail in PDF format. An originally signed face-page should be submitted via mail.

The MRF will not consider applications from those not holding faculty rank at Brown.

Members of the Brown community not holding faculty rank wishing to propose projects must arrange with a Brown-affiliated faculty member to submit a proposal to the MRF. The identified faculty member must agree to assume responsibility for projects initiated by Brown-affiliated individuals not holding faculty rank. The responsibility includes IRB submissions, supervision of research staff, and financial arrangements to use the MRF facilities.

Those outside the Brown community wishing to conduct MRI research under the auspices of the MRF must enter into a collaborative relationship with a Brown-affiliated faculty member. The identified faculty member must agree to assume responsibility for projects initiated by non-Brown-affiliated individuals. The responsibilities include IRB submissions, supervision of research staff, and financial arrangements to use the MRF facilities.

2. **CV:** A CV for the PI must be submitted via E-mail to the MRF (PDF format).
3. **Research Project Description.** A completed research project description must be submitted via E-mail to the MRF (PDF format). The description should include pertinent details about the

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scientific aims of the project and the MRI-related software and hardware used in the conduct of the research.

**4. IRB Approval for Projects Involving Human Subjects:**

Information about the procedures and policies related to obtaining IRB approval for research projects conducted at Brown University appears at the web site of Brown's Human Research Protections Office. <http://research.brown.edu/rschadmin/hrpo>.

Principal Investigators should refer to Exhibit B for more details about IRB procedures and policies.

Projects cannot become initiated or continued without relevant IRB approval. PI's must provide written documentation of the initial IRB approval(s) and annual IRB renewal(s).

- a. All research projects involving human subjects must have approval of the Brown University IRB.
- b. Researchers based at Brown-affiliated hospitals must also obtain IRB approval from their home institutions. With the exception of researchers based at Lifespan, the Brown IRB requires that IRB approval be obtained from the researcher's home institution prior to submission to the Brown IRB. Researchers at Lifespan should submit concurrent applications for IRB approval to Lifespan and to Brown.
- c. Researchers based at non-profit, non-Brown affiliated institutions must obtain and submit approval forms from their home institutions as well as from the Brown IRB and if applicable other relevant Brown-affiliated IRBs. These individuals must have a formal collaboration with a Brown-affiliated faculty member in order to conduct MRI research at Brown.
- d. Researchers based at for-profit, non-Brown affiliated institutions must obtain and submit approval forms from their home institutions as well as from the Brown IRB, and if applicable other relevant Brown-affiliated IRBs. These individuals must have a formal collaboration with a Brown-affiliated faculty member in order to conduct MRI research at Brown.

**5. IACUC Approval for Projects Involving Experimental Animals**

- a. All research projects involving experimental animals are required to have the approval of the Brown University IACUC.
- b. Researchers based at Brown-affiliated hospitals must also obtain approval from their home institutions to conduct research at Brown with experimental animals.
- c. Researchers based at non-profit, non-Brown affiliated institutions must obtain and submit approval forms from their home institutions as well as from the Brown IACUC for the conduct of research using experimental animals. These individuals must have a formal collaboration with a Brown-affiliated faculty member in order to conduct MRI research at Brown.
- d. Researchers based at for-profit, non-Brown affiliated institutions must obtain and submit approval forms from their home institutions as well as from the Brown IACUC for the conduct of research using experimental animals. These individuals must have a formal collaboration with a Brown-affiliated faculty member in order to conduct MRI research at Brown.

**6. Training Requirements**

This section provides basic orientation to the training requirements. Section 2 has a more extensive treatment of training.

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- a. MRI Safety Training. All individuals requiring access to the MRI facility for research and/or educational activities must complete MRI safety training appropriate to their role in the work (see Section 2, Training Requirements, for details).
- b. Human Subjects Training. All researchers having a protocol that involves human subjects are required to have completed the CITI training for research with human subjects (see Section 2, Training Requirements, for details).
- c. Experimental Animal Training. All researchers having a protocol that involves experimental animals are required to complete all necessary training for the proper use of experimental animals. The following URL provides guidelines <http://bms.brown.edu/iacuc/>
- d. Emergency Procedures Training. For all protocols involving human subjects, at least one researcher must be present during each MRI data acquisition session who has completed MRF emergency procedures training and is capable of assisting the MRI system operator in the event of an emergency.

**7. Insurance Requirements and Facilities Use Agreement for External Users:**

- a. All non-Brown employees must submit a completed MRI Facility Use Agreement (Exhibit C) prior to using Brown's MRI Facility. Non-Brown employees include all researchers employed at Brown-affiliated hospitals, all researchers at non-Brown, not-for-profit institutions, and all researchers based at for-profit institutions.
- b. The Facilities Use agreement must be signed by a person authorized to act on behalf of the researcher's institution. A copy of the Facilities Use Agreement may be found at the following URL : **<link to be supplied by Jeanne Hebert>**
- c. Insurance requirements and indemnification language will appear in the Facilities Use Agreement **<being drafted by JH>**
- d. Researchers wishing to obtain further information about the Use Agreement or insurance requirements should contact:

Jeanne Hebert  
Director, Insurance and Risk  
Box 1848, Brown University, Providence, RI 02912-1848  
(401) 863-3366  
E-mail : [Jeanne\\_Hebert@Brown.edu](mailto:Jeanne_Hebert@Brown.edu)

**8. Compliance.**

The MRF Administrative Assistant, working with the Director, and Associate Directors for Research and MRI Physics will work with all researchers on ensuring that they comply with all matters pertaining to safety training, insurance, IRB and IACUC approvals and other items requiring paper documentation. All Principal Investigators have an obligation to adhere to IRB approved procedures for research protocols. The Staff Administrative Assistant will not schedule requests to use the MRI system until all approvals have been submitted and then maintained in good standing. The Staff Administrative Assistant will communicate with the staff operating the MRI system the approval status of groups requesting instrument usage. A University official in the Office of the Vice President of Research will provide overall oversight to the compliance process and will ensure the assessment and documentation of staff compliance at least annually.

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**SECTION 2: PERSONNEL CATEGORIES AND TRAINING REQUIREMENTS**

This section details policies and procedures ensure the safe operation of the MRI research facility, to protect volunteers, to protect research personnel and staff and to safeguard the MRF infrastructure.

**PERSONNEL CATEGORIES**

The MRF has a categorical scheme for those who enter the MRI suite. The scheme has a hierarchical character with increasing levels of training and commensurate permission to use the facilities and facility equipment.

**Volunteer:** Individual who provides informed, written consent to participate in approved research protocols.

**Visitor:** Individual without any or incomplete training related MR safety, human subject participation or experimental animal research participation.

**Level 1:** Individuals who have passed safety and equipment training to ensure ones own safety during research-related activities within Zones 1 – 4 (see Section 3 for Zone definitions). Those Level 1 individuals involved with research with human participants will also have completed the CITI training regimen. Those working with experimental animals will follow Brown's IACUC rules for research with experimental animals. Level 1 individuals can enter all areas of the MRI Suite unescorted, but cannot escort Volunteers or Visitors into Zone 4 without the explicit consent and direction by a Level 3 individual.

**Level 2:** These individuals have all Level 1 training and have received more extensive MRI safety, participant screening, equipment training and knowledge of emergency procedures. These individuals have access to all areas of the MRI suite, but cannot operate the MRI system. Those working with experimental animals will follow Brown's IACUC rules for research with experimental animals.

**Level 3:** These individuals have all Level 1 and Level 2 training and have received more extensive MRI safety, participant screening, equipment training and knowledge of emergency procedures to allow for independent operation of the 3T MRI system. These individuals must have certification in Basic Cardiac Life Support (BCLS). Level 3 individuals have full privileges for operating the MRI system and access to all areas of the MRI suite. Those working with experimental animals will follow Brown's IACUC rules for research with experimental animals.

**Human Subjects Training.** Brown University and the MRF requires that all personnel involved in human subjects research complete the on-line Brown University/CITI Education Program in the Protection of Human Research Participants; this includes all faculty, students, and research staff. Information about this program may be found at

[http://research.brown.edu/rschadmin/hrpo\\_citi\\_menu.php](http://research.brown.edu/rschadmin/hrpo_citi_menu.php)

**MRI Safety Training.** All researchers planning to enter the MR suite in the Sidney Frank Hall of Life Sciences for the purposes of conducting research must complete Level 1 Basic MR Safety Training. Initial Basic Safety training will be done on-site by MRF staff and consists of a presentation that includes viewing of the Siemens safety tape and a slide presentation. This format

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will give individuals a chance to ask questions and get answers to any concerns that they might have. Initial training also includes a familiarization with the facility. All researchers will also be required to read a chapter on MRI safety. A paper or web-based assessment will be administered to document understanding of the critical issues. Once initial training is complete, refresher courses may be done entirely on-line.

Individuals completing Level 2 Advanced Safety Training receive more detailed training regarding safety procedures, subject screening procedures and emergency procedures. Certified Level 2 personnel are able to assist in the event of an emergency and, with the permission of the MRI system operator, are able to be responsible for accompanying a Volunteer into the MRI magnet room, can position the coils, and other equipment and can operate the table controls. Level 2 individuals undergoing training to advance to Level 3 status can operate the MRI system under the direct and constant supervision of a Level 3 trained individuals. Level 1 individuals undergoing training to advance to Level 2 status can position the coils, and other equipment and can operate the table controls under the direct of and constant supervision of a Level 2 or Level 3 individual.

**Emergency Procedures Training.** Level 2 and Level 3 personnel will receive instruction in procedures related to emergency situations involving medical emergencies (such as cardiac arrest) or those presenting an immediate threat to human life or to the facility infrastructure. This training is also available to other research personnel and encouraged for key leadership personnel for each laboratory group. As indicated in the section of MRI System Operation, at least two people will be required to be present for all MRI sessions in which there is a human subject, one of whom must have completed Emergency Procedures Training. Work involving materials or MRI phantoms can occur with a single, Level 3 trained individual who could work without an additional Level 2 person on-site.

**Additional Training for Level 3 personnel.** All Level 3 personnel must have current Basic Cardiac Life Support (BCLS) and basic First Aid/Life Support certification. This training may be arranged through the Emergency Medical Services of Brown University.

**MRI system operations.** At the discretion of the MRF, certain non-MRF research personnel may be trained and certified to operate the MRI system, thus to reach Level 3. Only Brown-employed faculty, post-doctoral fellows and other personnel as specifically approved by the university may be certified to operate the MRI system unaccompanied by a Level 3 certified MRF staff member. MRI system operation and related training will be conducted by the Facility Manager. Certification to operate the MRI system will be conferred by the Associate Director for Research and the Medical Director upon the determination of competency and recommendation of the Facility Manager, approval of the Education and Training Advisory Committee and the Safety Advisory Committee (see MRF web site for Committee descriptions, <http://brainscience.brown.edu/MRF/index.htm>) and upon completion of a competency exam. The training will involve on-site observation and supervised practice in the operational procedures of the MRI system, and safety and emergency protocols. Anyone certified to operate the MRI system must also have received Emergency Procedures Training.

**Renewal of MRI Safety Training.** Biennial web-based refresher training will be required of all certified research personnel. Additional ad hoc training may occur due to newly developed safety guidelines.

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**TRAINING PROGRAM CONTENTS**

**Level 1 Training: Basic Safety**

- Attend safety lecture – part 1
- Watch Siemens safety video
- Read MRI Safety section from Huettel textbook
- Site specific orientation
- Emergency evacuation plan
- De-metaling

**Level 2 Training: Advanced Safety**

- Attend safety lecture – part 2
- Subject screening procedures
- Squeeze ball
- Subject preparation
- Patient table controls
- Hearing protection
- Emergency procedures
  - Location and use of Emergency Power Shutdown Buttons
  - Location and use of Magnet Stop buttons
  - Patient table emergency release
  - Medical Emergency procedure
  - Quench procedure

**Level 3 Training: Scanner Operations**

- Minimum 6 hours of shadowing Level 3 MRF personnel performing magnet operations
- System start-up and shut-down procedure
- Routine scanning
- Patient table controls
- New patient registration
- Protocol selection
- Prescription
- Measurement (scanning)
- Data archival and retrieval
- Printing images
- Logging
- Patient monitoring (intercom) system
- Incidental finding protocol
- Oxygen sensor location
- Coil handling and storage
- Linens storage and use
- Knows how to access data on cryogen levels
- Knowledge of SAR and stimulation warnings
- QA procedures
  - Phantom placement and scanning

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**Orientation for non-Research Personnel**

Non-research personnel (such as custodians and other members of the Facilities Management team) who may require routine access to Zones 2 and 3 must receive an orientation that includes

- Basic familiarity with the hazards associated with the magnetic field
  - Missile effect
  - Malfunction of implanted medical devices
- Familiarity with the layout of the suite
  - Location and meaning of safety Zones
  - Location of scanner
- Instruction to attend to and obey all posted signs
- Instruction not to enter any Zone 4 area.

## SECTION 3: SITE ACCESS AND RESTRICTION POLICY

This section describes procedures designed to ensure a safe MR environment by maintaining controlled access to areas assigned to the MRF in and around the MRI suite.

### MRF SAFETY ZONES

The MRI suite in the Sydney Frank Building is divided into four safety zones as indicated on the attached Safety Zone Map (Exhibit D). These zones are labeled 1-4 and each zone represents a progressively greater level of access restriction.

#### **Zone 1:** Areas with unrestricted access

- All office and data analysis space allocated to the MRF (rooms 123, 125 and 129)
- All other adjacent public space such as corridors, rest rooms, stairwells and elevators.

**Zone 2:** Interface between public areas and restricted areas. Although this is a restricted area, visitors and volunteers do not require an escort in Zone 2.

- The wait-entry area of the MRI Suite (Room 126)
- Test Room (126B); normally locked with a physical key
- Toilet / Change Room (Room 126A)

**Zone 3:** Highly restricted area (magnetic field < 5 gauss). All visitors and volunteers in Zone 3 require escort by authorized personnel to enter this zone.

- 3T Control Room (Room 124)
- Secondary Entry Room (Room 122)
- Future 9.4T Control Room (Room 120)
- MRI Prep Lab (Room 118)
- Storage Room (Room 118A)

**Zone 4:** Exclusion area, potentially hazardous zone (magnetic field > 5 gauss). **All** persons entering Zone 4, including researchers, volunteers and special visitors **must** fill out and sign an appropriate screening form. No volunteer or special visitor is permitted in any Zone 4 area unless accompanied by a Level 1 or above certified individual.

- 3T MRI Scanner Room (Room 124A)
- Equipment room (Room 122A)

Appropriate warning signs about magnetic fields are posted at entry points to Zone 2 and Zone 3. Zone 4 is clearly marked as a potentially hazardous due to the presence of the magnetic field. Entrance to magnet room is marked with signage stating "The magnet is always on".

### KEY ACCESS

Access to most areas of the MRI suite is controlled by card key access. Card Key access points are shown on the Safety Zone Map (Exhibit D). Authorization for card key access to the MRI suite must be signed by an appropriate official in Biomed Facilities and by either the MRF Director or Associate Director of Research.

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- Card Key Level 1: Access to all entrances to the MRI suite from public areas.
- Card Key Level 2: Access to the Equipment Room (122A)
- Card Key Level 3: Access to the 3T Control Room

Access to the 3T Scanner Room (124A) is by physical key only.

The side door of the magnet room opening into Room 122 can only open from the inside of the magnet room; no key access will be possible. This door will be used only for transport of experimental animals into and out of the magnet room and for emergency egress if needed. In no case should this door be propped open.

**PROCEDURES FOR PERSONNEL AND ZONE RESTRICTIONS:**

Maintaining site access restrictions:

- a. Zone 1 has open access for all individuals permitted to enter Brown-owned buildings. In the relevant portion of Sidney Frank Hall, Zone 1 comprises the entrance, corridors, and other public areas in the immediate vicinity of the MRI suite.
- b. Volunteers, visitors and unaccompanied Level 1 individuals will enter the MRI suite only via the Wait Entry area (Room 126) from the public corridor.
- c. Only Level 2 and Level 3 personnel will have unrestricted access to Zone 3 areas. Level 1 personnel can enter Zone 3 areas only with prior permission from those with Level 2 or Level 3 training.
- d. The current operator of the MRI system has full responsibility for controlling access to Zone 4 areas, particularly the MRI magnet room.
- e. Any volunteer entering the magnet room must be accompanied by a certified Level 1, 2 or Level 3 individual and only with the permission of an on-site Level 3 individual. Note that under all circumstances ultimate responsibility for the volunteer remains with the on-site Level 3 individual currently in charge of the MRI system.
- f. Volunteers are not permitted in the Equipment Room.
- g. Visitors and Volunteers may only enter Zone 3 with the escort of a certified Level 1, Level 2 or Level 3 individual.
- h. Generally, Visitors are not permitted in Zone 4. Visitors that can enter Zone 4 include parents or guardians of special populations, such as minors and volunteers with diminished cognitive capacity; vendors of specialized MRI-related equipment or University staff or guests that have special needs to enter the magnet room (Room 124A) or Equipment Room (Room 122A). Visitors that intend to enter the magnet room must be screened for MRI safety and sign a completed screening form prior to entering the MRI magnet room (Room 124A) or Equipment Room (Room 122A).
- i. All research staff participating in the conduct of an IRB approved research protocol on the premises of the MRI Suite must have at least Level 1 status. The PI of a laboratory will designate one or more individuals with Level 1, Level 2 or Level 3 status who will assume responsibility for that laboratory's conduct of MRI data acquisition. These individuals must be present during MRI data acquisition for that laboratory's experiments. The PI of the laboratory may designate personnel who will become trained to Level 2 or Level 3 competence. If laboratory personnel attending an experimental session have varying levels of competence, the laboratory member with the highest level of competence will assume overall responsibility for

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that laboratory's conduct of MRI data acquisition during that particular session. Laboratory, non-MRF, Level 2 or Level 3 individuals will interface with the MRF in the proper conduct of MRI data acquisition policies and procedures, including who will operate the MRI system for a particular session. Laboratory Level 2 or Level 3 individuals may have access to doors from the corridor to Rooms 118 and 122 at the discretion of the Associate Director for Research.

Screening procedure:

All individuals, including volunteer research participants, visitors, technologists, researchers, ancillary support staff, custodial workers, and maintenance and service providers, must be oriented and verbally pre-screened for MRI safety prior to admittance into Zone 3. The pre-screening will focus on metallic and electronic implants; those individuals with metallic or electronic implants will be informed to stay away from any areas marked within the 5 gauss line. No person may enter Zone 4 without proper and full MR safety screening as described above. Section 7 provides additional details about the screening procedures.

Pregnancy

Pregnant women are not permitted in the magnet room during scanner operation, except in cases where IRB approval to include pregnant women in experimental procedures has been sought and approved. Pregnant women can enter Zone 4 when the magnet is not operating.

**EQUIPMENT CATEGORIES**

The MRF has two general types of equipment: MRI equipment and non-MRI equipment

MRI equipment: This equipment includes all hardware related to acquisition of MR images. It includes the MRI system, MRI coils and gradient inserts, animal holders for insertion into the magnet bore.

Non-MRI equipment: This equipment includes all equipment used to present stimuli and collect data about behavioral and/or physiological responses in support of acquisition of MR images. Such equipment includes LCD projectors, blood pressure monitors, and push buttons.

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**SECTION 4: MRI SYSTEM OPERATION**

This section describes the procedures and policies for operating the 3T MRI system safely and effectively according to an established set of criteria that defines who may operate the MRI system.

**Definitions:**

MRI SYSTEM: Siemens 3T TIM Trio

RESEARCH AGREEMENT: Contractual agreement between Siemens and Brown on providing services and materials between the two organizations.

PRODUCT: MRI sequences or hardware provided by the manufacturer (Siemens); these have received full FDA review and approval.

PROTOTYPE: MRI sequences or hardware provided by Siemens that is a first of its kind for test; the software or hardware has followed FDA guidelines but has not received review or approval.

WORKS-IN-PROGRESS (WIPs): MRI sequences and hardware that is provided by the manufacturer according to terms of a research agreement; the software or hardware has followed FDA guidelines but has not received review or approval.

CUSTOM: MRI sequences and hardware written or constructed, respectively, at Brown or by third-party vendors or collaborators. The software or hardware has followed FDA guidelines but has not received review or approval.

SENIOR GRADUATE STUDENT: Student who has achieved candidacy for the Ph. D. degree.

**MRF oversight.** The MRF has established a structure to provide oversight to operation of the MRI system. The MRF oversight does not override existing University or IRB policies. The Education and Training Advisory Committee and Safety Advisory Committee of the MRF will have joint oversight regarding to the safe operation of the 3T MRI system. (See MRF web pages for a description of the charge to these committees and their membership.) The Safety Advisory Committee will set policies for the operation of the MRI system; these policies will undergo annual review, though procedures can be modified at any time when new safety concerns arise. The Education and Training Advisory Committee will implement training procedures established by the Safety Advisory Committee for Level 1, Level 2, and Level 3 personnel so as to ensure proper use of equipment and implementation of MRF procedures. Both Committees must agree to certify a user for independent operation of the MRI system.

**Operation by MRF Personnel.** Only Level 3 personnel can operate the MRI system. A Level 3 individual will have received specific training in operation of the 3T MRI system and have received certification by a consensus agreement of the Education and Training Advisory Committee and the Safety Advisory Committee. A second individual with Level 2 or above training must be present to assist the Level 3 operator during MRI system operation with human volunteers or experimental animals.

**Brown-affiliated, non-MRF research personnel** may receive training to Level 3 competence and certification to operate the MRI system, with the assistance of a second individual with Level 2 or above training. Only Brown-employed faculty, post-doctoral fellows and other personnel as specifically approved by the university may be certified to operate the MRI system unaccompanied by a Level 3 individual that is part of the MRF staff. Requests by non-MRF research personnel to receive and certification to operate the MRI system will undergo review by the Education and Training Advisory Committee and Safety Advisory Committee. Note: The MRF Director, Associate Directors and Facility Manager reserve right to refuse permission for anyone to operate the scanner.

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**Siemens engineering personnel** may operate the MRI system in accordance with the manufacturer's service agreement.

**Training procedures.** Training and certification in the operation of the MRI system will follow the procedures outlined in Section 2, Training Requirements, *MRI system Operations*. Unless otherwise specified, certification will apply to product sequences only (see next section).

**Experimental MR software and hardware.** Most researchers will use 'product' software and hardware. However, some researchers will use non-product WIPs, prototype, or custom software and hardware, only with IRB approval. Use of prototype, WIP, and custom software will require a password, entered on the MRI system control console. This password will be disseminated only to those researchers and MRF personnel that require use of the WIPs or prototypes. Size permitting, prototype, WIP, or custom hardware will be stored in a locked area, available only to those researchers designated for its use. The Education and Training Advisory Committee and Safety Advisory Committee will determine who will have access to the password(s) required to implemented non-product MR sequences. These Committees will work together to assign passwords. Non-product hardware of sufficient small size will be stored in locked areas; access to these areas will be determined conjointly by the Education and Training Advisory Committee and the Safety Advisory Committee. Large non-product hardware will be stored in the Zone 3 or Zone 4 areas, which is always under the control of a Level 3 individual. Hardware not stored in secure cabinets or rooms will have some other mechanism to secure them to prevent unauthorized use customized to the piece of hardware. .

**Compliance.** Use of the MRI system will ultimately be controlled and monitored by access software (to be developed). This software will create logs of MR pulse sequences and hardware used for each experimental session. Logs will be reviewed weekly by MRF personnel, including the Facility Manager and the Associate Director of Research. Prior to developing a software log system, the MRF will have a paper-based log of system use.

## **SECTION 5: EMERGENCY RESPONSE**

This section will describe procedures and policies relevant to life threatening emergencies at the Brown University 3T MRI suite by identifying responsibilities and authorizing staff to institute emergency measures per established American Heart Association protocols within the scope of his/her demonstrated competence.

### **Medical Emergency**

1. In the event of a medical emergency, the MRI system operator will instruct the second individual, who is required to be present for all human studies, to call Brown Public Safety at x3-4111 from a campus phone (863-4111 from a non-campus phone), and to identify the event and location (Sidney Frank Hall for Life Sciences, Room 124A). Emergency Response personnel should be directed to the entrance closest to the MRF facility. If the research participant is within the bore of the MRI system, the MRI operator/designee will engage TABLE STOP and manually pull the research participant out of magnet bore.
2. The operator will then transfer the research participant to a non-ferrous stretcher that will be available in the magnet room.
3. The operator will then remove the research participant from the magnet room to the Zone 2 Wait Entry Room (Room 126).
4. The operator will then secure the magnet room door to prevent entry by first responders. The MRI system operator is responsible to ensure no one enters magnet room without proper screening for MRI safety.
5. An on-site individual certified in BCLS will start CPR if necessary.
6. A technologist assistant or designated staff member will meet the emergency responders at the entrance to the building outside of the vestibule on the 1<sup>st</sup> floor West Wing, Room 128. The designated staff member will guide the emergency response team through the entrance vestibule, Room 128, into the holding area designated as Wait Entry, Room 126.
7. The MRF staff or Laboratory personnel will cede responsibility to emergency responders as they enter the Wait Entry Room, Room 128, assisting the 1<sup>st</sup> responders as requested.
8. The MRF staff will file an incident report and notify appropriate University personnel. The following should be notified:
  - a. Brown University Department of Public Safety.
  - b. Brown University Office of Environmental Health and Safety
  - c. Brown University Office of the Vice President for Research
  - d. Brown University Office of Insurance & Risk (if involving injury or which may result in an insurance claim).

### **MRI system quench**

The MRI magnet is maintained at a high field strength by means of super-cooling its conductive loops of wire with liquid helium, which is at an extremely low temperature – close to absolute zero (about 4°K). In certain circumstances, this helium may be rapidly vented off, warming the magnet and causing it to quickly lose its magnetic field. This is known as a “quench.” A quench may be initiated either in a controlled fashion by pressing one of the two Magnet Stop buttons, in which case the helium is safely vented to the outside of the building or, in extraordinary situations, such as an earthquake or an explosion, it is possible for an uncontrolled quench to occur, in which case the helium may vent into the room making breathing difficult.

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### Controlled quench

A controlled quench should only be initiated by authorized personnel in the event of a potentially life-threatening emergency, such as an individual in respiratory distress being pinned to the magnet by a metallic object. A quench of the magnet is extremely expensive and has the potential to damage the equipment. In non-life threatening situations, such as a piece of equipment being pinned against the magnet no one should initiate a quench. If it is determined that a potentially life-threatening situation exists, the operator or his designee should:

1. Evacuate the magnet room, if possible
2. Depress one of the two Magnet Stop buttons. One is located on the wall of the magnet room and the other is to the left of the operator console. Both are located under plates of Plexiglas, which must be lifted, to prevent them from being pressed accidentally.
3. The magnetic field will dissipate in approximately one minute.
4. If the quench was initiated because of a medical emergency, the procedures listed above under Medical Emergency should be followed.
5. After ensuring Zones 3 and 4 are secure and that all individuals have exited these areas, inform Siemens of the quench. (see attached zone map for definitions of facility zones; Exhibit D)
6. File incident report and notify appropriate University personnel. The following should be notified:
  - Brown University Department of Public Safety.
  - Brown University Office of Environmental Health and Safety
  - Brown University Office of the Vice President for Research
  - Brown University Office of Insurance & Risk (if involving injury or which may result in an insurance claim).

### Uncontrolled quench

1. In the event of a spontaneous 'quench' of the MRI system; that is, a total venting of the liquid helium, and the research participant or experimenters are within the room containing the MRI system, the first MRF staff to arrive will immediately implement the evacuation of everyone from Zones 3 and 4 of the area. Once all individuals have exited from Zones 3 and 4, the MRF staff will call Brown Public Safety at x3-4111 from a campus phone (863-4111 from a non-campus phone). Public Safety should be asked to contact Brown Environmental Health & Safety or MRF staff can contact them directly by calling the 24-hour emergency contact pager number: 745-7359.
2. If a volunteer or another individual becomes incapacitated due to the quench, the first MRF staff to arrive will transfer the research participant and others to a non-ferrous stretcher, located in the magnet room.
3. Remove research participant and others from magnet room.
4. Secure magnet room door. The MRI magnet operator is responsible to ensure no one enters magnet room without proper screening for MRI safety. Note that even in the event of a quench, a significant magnetic field may remain for some period of time.
5. Certified individuals start CPR if necessary.
6. Technologist assistant or designated staff member meets emergency responders at MRI entrance to building. Designated staff member guides team through entrance VESTIBULE 128 into holding area designated as WAIT ENTRY 126.
7. Emergency resuscitative efforts to be run in waiting area 126 adjacent to MR suite. Technologist and assistant/designated staff member assist with Emergency Response personnel as needed.
8. After ensuring Zones 3 and 4 are secure and that all individuals have exited these areas, inform Siemens of the quench.

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9. File incident report and notify appropriate University personnel. The following should be notified:
- Brown University Department of Public Safety.
  - Brown University Office of Environmental Health and Safety
  - Brown University Office of the Vice President for Research
  - Brown University Office of Insurance & Risk (if involving injury or which may result in an insurance claim).

### **Electrical Fire**

1. In the event of that smoke or flames are detected in the vicinity of the electrical equipment, the operator should press the red Emergency Power Shutdown button (**NOT** the red quench button) located in the control room or in the magnet room.
2. Follow standard evacuation procedure (see below).

### **Evacuation Procedure**

1. All personnel will have read University prepared documents on emergency procedures, attended training on the University Emergency Action Plan and have familiarity with general policies as they apply to the MRI Suite. Link to the following URL to download the University Emergency Action Plan:  
[http://www.brown.edu/Administration/EHS/restricted/emergency\\_action\\_plan.pdf](http://www.brown.edu/Administration/EHS/restricted/emergency_action_plan.pdf)
2. The MRI system operator is required to securely lock the door to the magnet room to ensure that no emergency personnel or unscreened emergency equipment are accidentally exposed to the standing magnetic field of the MRI system.
3. In the event of fire in the area of the MRF suite or if it is known that a fire alarm was activated in or near the MRF suite, a member of the MRF staff should proceed to the Meeting Street entrance of the Sidney Frank Hall to meet Brown Public Safety and Providence Fire Department personnel to provide warning and MRF suite information.
4. All personnel should evacuate the building through the nearest exit (through Entry Vestibule 128), which is located directly to the right as one exits the MRF suite into the main corridor.
5. All personnel should proceed to the assigned meeting area, directly across Meeting Street in front of Alumnae Hall to verify personnel accounting.
6. Do not reenter the building until granted permission by the Fire Department.

### **MRI system malfunction**

In the event that the MRI system malfunctions, the operator-in-charge must log a service call to the service arm of Siemens Medical Solutions by calling Siemens "Up-Time" at 800-888-7436. Non-exhaustive reasons for logging a service call include the following, failure to boot or reboot the MRI system; system default messages; magnet stop alarms; and chiller malfunctions. The TIM Trio in the Sidney Frank Hall of Life Sciences has the following number, which is required when logging a service call: 181235.

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**SECTION 6: MRI EQUIPMENT SAFETY INSPECTION AND STORAGE POLICY**

This section provides policies and procedures for handling equipment in the MRI area. The section aims to establish a protocol for the detection of metallic (ferrous) objects prior to entering the area of the MR system to prevent injuries or damage related to the “missile effect”.

**Definitions:**

FERROUS is defined as a property of some substances including iron and some alloys, in which the application of a weak magnetic field induces high magnetism. Iron, cobalt and nickel are ferromagnetic metals.

MISSILE EFFECT is the result of the fringe field attracting ferromagnetic objects into the MR system with considerable force. Generally, the force increases as the distance between the object and the magnet bore entrance decreases.

**PROCEDURES:**

1. All ancillary equipment and supplies to be housed in the area of Zone 3 that could potentially be brought into Zone 4 must be clearly labeled ***MRI Safe*** or ***MRI Not Safe***. Tags with large print will become affixed to all such devices brought into Zone 3.
2. Any temporary equipment or supplies must be inspected for ferrous properties by trained MR staff. A hand-held magnet will be located in Room 124 for this purpose.
3. Only ***MRI Safe*** equipment and devices are permitted in Zone 4 (MRI system room).

**4. WARNINGS:**

- Magnetized objects introduced into the magnetic field become projectiles. Device malfunctions can occur.
- Devices used in the MRI system room must be compatible with the field strength of the MR system.
- Devices compatible with 1.5T systems may be unsuitable for 3T.
- Injury to research participants and personnel can occur if resuscitation systems, defibrillators, or metallic crash carts are brought into the MRI system room.

## **SECTION 7: RESEARCH PARTICIPANT SCREENING AND SAFETY GUIDELINES**

The following establish guidelines designed to prevent accidents due to interactions with the MR magnetic field and the MR system. The policy covers research participants, experimental animals and research staff regarding procedures related to MR imaging. These guidelines will ensure a participant's safety by implementing a complete and effective MR safety screening process. Additionally, this document provides MR staff, researchers, and support staff with specific guidelines regarding exclusions for MR procedures.

### **Definitions**

MRI: Magnetic Resonance Imaging

SCREENING: Interview process in which a volunteer is asked for pertinent health and lifestyle information that could indicate a contraindication to exposure to the static and gradient magnetic fields.

EXCLUSION CRITERIA: Designated standards established by ACR guidelines as unsafe for an MRI exam.

### **Screening Forms**

One of the two approved screening forms will be used to screen an individual for MR safety depending on the person being screened.

Screening Form for Volunteers (Exhibit E). This form **must** be used for any individual who will be undergoing an MRI scan. The form must be signed and dated by both the volunteer and by the individual doing the screening. This form will also be used for a parent or guardian that will remain in the magnet room during the conduct of a MRI session.

Screening form for non-Volunteers (Exhibit F). This form, an abbreviated version of the screening form for volunteers, may be used for any individual (researchers or visitors) that will **not** have an MRI scan but who will be entering an area for which screening is required. It is acceptable to use the form for Volunteers for non-Volunteers, however, anyone who will be going in the scanner must be screened with the form for Volunteers.

### **Prescreening**

Researchers are encouraged to prescreen their volunteers for MRI contraindications prior to scheduling them for scanning. Prescreening lessens the chance that scan sessions will have to be cancelled at the last minute because of volunteer MRI incompatibility thereby causing inconvenience to staff, researchers and to the volunteer. Researchers will be charged for such last minute cancellations. Prescreening may be done verbally or in writing and the researcher is not required to submit a copy of any prescreening paperwork to the MRF. NOTE: All individuals **must** be formally screened on-site according to the procedures outlined in this section prior to entering Zone 4 regardless of whether or not they have been prescreened.

### **Human Research Participant Screening**

At the time of check-in at the MR site, participants arriving for an MRI procedure are asked to complete a screening form to determine the presence of ferromagnetic and other metallic objects (Exhibit E). In practice, all participants will have previously undergone a MR safety pre-screening to identify potential contraindications for an MRI procedure prior to scheduling. The pre-screening is done by the research group. The on-site screening is supervised by the individual responsible for operating the MRI suite. The screening form must be signed by both the research participant and by the magnet operator and a copy of the form will be kept on file at the MRF. All non-research personnel entering the magnet room must be screened at each visit even if they have previously filled out a screening form on a prior visit. If

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a research participant does not have the mental capacity to answer the screening questions on the form or is underage, then a family member, a guardian, or a healthcare professional will assist in completing the screening form accurately. Interpreters must be provided if needed to complete the screening process for those without adequate English language competence. The research assistant/responsible party will review the screening form and alert the MRI system operator if the volunteer has indicated any potential risk factors on the form, following guidelines as stated below. The MRI system operator will additionally verbally screen the volunteer prior to entering the magnet room. The MRI system operator is ultimately responsible for ensuring that all persons entering the magnet room have been properly screened.

Pregnancy. Females that self-report pregnancy will be excluded from participation unless the protocol specifically has pregnancy as an inclusion criterion.

### **Visitor Screening.**

With minor exceptions, no visitors can enter the magnet room. Exceptions include parents of children receiving an MRI and guardians or obligatory health-care providers of demented research participants or special University officials or guests. As noted above, these individuals will undergo MR safety screening equivalent to that for research volunteers. In some other cases, equipment vendors or visiting researchers may enter the magnet room when accompanied by MRF personnel. These special visitors must also undergo MRI safety screening and complete and sign a screening form. The MRI Screening form for Non-Volunteers may be used for this purpose.

### **Medical devices and objects**

If the research participant or visitor indicates having the presence of an implanted medical device on the MR screening form, it is obligatory to obtain the exact name of the device and the manufacturer prior to entry into Zone 4. This information is necessary for the MRI system operator or researcher to verify MR compatibility of the implant or device in the Reference Manual for Magnetic Resonance Safety by Frank G. Shellock, Ph.D.<sup>1</sup> or by accessing the MR safety web site ([www.mrisafety.com](http://www.mrisafety.com)), or by contacting the manufacturer of the implant directly to confirm safety testing at 3T. Any documentation will be attached to subjects screening information to be filed with consent forms.

For all MR studies, information identifying an implanted object or device must be documented in writing on the MRI Screening Form (Exhibit A). This information can be obtained from the operative notes in the volunteer's medical record or from implant identification cards.

Object Categorization: Objects are categorized by a status designation (see <http://www.mrisafety.com/list.asp>): Safe, Conditional 1-5, Unsafe 1-2.

1. Participants with implanted Safe Objects/devices may have an MRI.
2. Participants with implanted Objects/devices listed as Conditional 1 may have an MRI.
3. Participants with implanted Objects/devices listed as Conditional 2 may have an MRI.
4. Participants with implanted Objects/devices listed as Conditional 3 refer to transdermal medication delivery patches. All such patches must be removed prior to an MRI procedure. A new patch should be applied after the MRI procedure is complete.
5. Participants with implanted Objects/devices listed as Conditional 4 refer to a halo vest or cervical fixation device. This is known to have ferromagnetic component parts, however, the magnetic field interactions have not been determined. These participants will not have an MRI.
6. Participants with implanted Objects/devices listed as Conditional 5 can not have an MRI.
7. Participants with implanted Objects/devices listed Unsafe 1 or Unsafe 2 can not have an MRI.

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**Tattoos**

Tattoos are not a contraindication for MRI procedures. Heavily tattooed individuals should be instructed to be alert for any heating sensations and to notify the magnet operator (by using the squeeze ball) should they experience any discomfort. Participants with tattoos may or may not have an MRI based on the opinion of the magnet operator or the researcher.

**Orbital (Eye) considerations** (applicable to human participant studies only)

Orbital injury. If a research participant reports on the screening form a history of metallic injury to the eye, the participant will be excluded from participating in the MRI study.

Orbital metal exposure. If a research participant indicates a history of metal work on the screening form, the researcher/MRF staff will alert the technologist/responsible person. The technologist will interview the research participant to determine if s/he ever had an injury to the eye from such metal work, and if the research participant always wore safety glasses or goggles while doing this work. The technologist will document the research participant's answer on the screening form. If the research participant states that s/he did not always wear eye protection wear while cutting, grinding, or welding metal, the research participant will be excluded. If the research participant states that s/he always wore eye protection, and is certain that s/he never got a metallic foreign body in the eye, the MRI procedure may be performed.

**Post operative conditions.** (Applicable to human participant studies only)

If a volunteer has a heart valve, coronary artery bypass clips, IVC filter, limb or joint replacement or pinning, spine fusion or Harrington rod or intra-abdominal clips, applicable MR compatibility and the date of the surgery must be known.

Pacer wires in the chest are a contraindication for an MR exam.

**Hearing Protection**

All volunteers and all visitors or researchers that will remain in the magnet room during scanning are required to wear hearing protection in the form of ear plugs, sound-attenuating headphones, or both. Any protocols requesting that hearing protection not be used must be specifically approved by the IRB and by Brown EH&S.

**Final preparations.** (Applicable to human participant studies only)

Before entering Zone 4 of the MR suite, research participants must remove metallic objects from their person including: jewelry, bobby pins, barrettes, wigs or hairpieces, coins, pens, pencils, paper clips, lighters, keys, wallets, credit cards, belts, zippers and all other potential hazardous objects or apparel.

Following recommendations set by the ACR, all research volunteers may be required to remove street clothing and change into clothing provided by MRF facility. To prevent sub-optimum imaging due to artifacts, the magnet operator or assistant will prepare research participants for all MRI procedures by requiring removal of any articles of clothing adorned with zippers, snaps, hooks, appliqués or fabric containing nylon or satin. Heavy applications of make-up must be removed upon the judgment of the magnet operator or researcher. Additionally, the magnet operator or assistant will ensure research participants that will undergo head MRI to remove dentures, partial plates and retainers before the MRI exam.

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### **Experimental Animal Screening**

Experimental animals will undergo screening similar to humans, except that the research group will provide answers to the relevant queries about MRI safety. If needed the staff of the Animal Care Facility will interact with the MRF to insure MRI safety of experimental animals.

### **Incidental Findings with human or experimental animal participants**

1. Identification of potentially abnormal finding while the research participant is still undergoing an MRI procedure. The operators may elect to stop the procedure if s/he notes a potential structural or functional abnormality. At the end of the procedure, the operator will contact the MRF Medical Director and provide relevant images so as to allow formation of an opinion as to whether the research volunteer should seek a medical opinion about the perceived abnormality. Current IRB policy holds that no research-related images can be provided for diagnostic purposes.
2. Identification of potentially abnormal result after the research participant has left the facility. At the end of the procedure, the operator will contact the MRF Medical Director and provide relevant images so as to allow formation of an opinion as to whether the research volunteer should seek a medical opinion about the perceived abnormality. Current IRB policy holds that no research-related images can be provided for diagnostic purposes.

### **Incident Reports**

1. An incident report must be submitted when an event occurs that has potential consequences for the infrastructure of the facility or for any adverse event involving a human research volunteer or an experimental animal.
2. A non-exhaustive list of incidents includes: hearing loss possibly related to the MRI sequence generation; heating of skin; ferromagnetic objects striking a research participant; equipment failure that has potential to injure a research participant; death of an experimental animal due to the procedures, etc.
3. The magnet operator must file a report of the incident, co-signed by the relevant PI and laboratory member in charge of the experiments. This report should be submitted to the MRF Administrative Assistant who will notify the MRF Director, the Associate Directors for Research and MRI Physics and the Chair of the Safety Advisory Committee.
4. Reports should be submitted internally to the MRF within 24 hours. MRF reports to other bodies, such as the relevant IRBs should occur within three (3) business days. Copies of the reports to the relevant IRBs will go to the following Brown offices:
  - Brown University Department of Public Safety.
  - Brown University Office of Environmental Health and Safety.
  - Brown University Office of the Vice President for Research
  - Brown University Office of Insurance & Risk (if involving injury or which may result in an insurance claim.)

1. Sherlock, Frank G., Ph.D. Reference Manual for Magnetic Resonance Safety: 2003 Edition. Amirsys, Inc.