Policies and Procedures Manual

BROWN UNIVERSITY MRI RESEARCH FACILITY

Institute for Brain Science

Sidney Frank Hall for Life Sciences

Prepared by MRF Staff and Associates

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SECTION 1: RESEARCH PROTOCOL REQUIREMENTS

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

Prospective researchers must submit application paperwork to the MRF for approval and provide documentation that they have obtained necessary IRB and/or IACUC approval, 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:

MRI Research Facility
185 Meeting Street
Brown University, Box G-LN
Providence, RI 02912

The application and approval process is as follows:

1. **MRF Application Form**

   A completed application form 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 form may be downloaded in PDF or Word format from

   http://mri.brown.edu/docs/

   The MRF will not consider applications from those not holding faculty rank at Brown. The MRF does not consider postdoctoral fellows as having faculty rank.

   Members of the Brown community, including Brown-affiliated hospitals not holding faculty rank wishing to propose projects must arrange with a Brown-affiliated faculty member to submit a proposal to the MRF. 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 have a Brown-affiliated faculty member co-sponsor the project. 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 1-2 page research project description must be submitted via E-mail to the MRF (PDF format).
4. **IRB Approval for Projects Involving Human Subjects**

   * Projects involving human subjects must have relevant IRB approval. PI's must provide written documentation of the initial IRB approval(s) and annual IRB renewal(s). Specific information regarding the IRB process for studies to be conducted at the MRF may be found at the Brown Research Protections Office web site:

     http://research.brown.edu/rschadmin/hrpo_mri.php

   * All research projects involving human subjects must have approval of the Brown University IRB.
   * Researchers based at Brown-affiliated hospitals must also obtain IRB approval from their home institutions.

* 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.
* 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.

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

* All research projects involving experimental animals are required to have the approval of the Brown University IACUC.
* Researchers based at Brown-affiliated hospitals must also obtain approval from their home institutions to conduct research at Brown with experimental animals.
* 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.
* 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.

6. **Training Requirements**

- 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).

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

All non-Brown employees must have a completed MRI Facilities Use Agreement in place between Brown and their home institution. The Facilities Use agreement must be signed by a person authorized to act on behalf of the researcher's institution.

Researchers wishing to obtain further information about the Use Agreement or insurance requirements should contact:

Brown University
Office of Insurance and Risk
Box 1848, Brown University, Providence, RI 02912-1848
401-863-9481

8. **Compliance**

The MRF Administrative Assistant along with the MRF Director, the MRF Facility Manager, the MRF Associate Director for Research and the MRF Associate Director for MRI Physics will work with all researchers on ensuring compliance with all matters pertaining to safety training, insurance, IRB and IACUC approvals and other items requiring paper documentation. 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 the approval status of groups requesting instrument usage to the staff operating the MRI system. 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. The Office of the Dean of Medicine and Biological Sciences is responsible for oversight of the MRI Research Facility. Periodic review will be conducted by the Office of Environmental Health and Safety at least every two years.

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. This category also includes individuals being scanned for the purposes of testing scanner protocols or equipment. Such individuals are required to complete a Brown-approved waiver form.

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

Level 1: Individuals who have passed safety and equipment training to ensure one's safety during research-related activities within Zones 1 – 4 (see Section 3 for Zone definitions). Level 1 individuals can enter all areas of the MRI Suite unescorted, but cannot enter the scan room without the approval of Level 3 personnel and 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. 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 as directed or delegated by the scanner operator and can operate the table controls.

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.

TRAINING

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 video and a slide presentation. This format 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. 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 as directed by the scanner operator 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.

Scanner Operator Training. MRI system operation and related training will be conducted by the Facility Manager. Certification to operate the MRI system will be conferred upon the determination of competency and recommendation of the Facility Manager, approval of the Safety, Education and Training Committee and the MRF Medical Director. 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 (see next section).

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, at least one of whom must be Level 3 and both 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.

Basic cardiac life support certification. All Level 3 personnel must have current Basic Cardiac Life Support (BCLS) certification. This training may be arranged through the Emergency Medical Services of Brown University.

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

Training Documentation. Documentation for each individual certifying the date of completion for each level of training is signed by the MRF Facility Manager or MRF Director of Research and retained by the MRF.

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 (positioning, coil connection, earplugs, etc.)
* 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 Specific Absorption Rate (SAR) and stimulation warnings
* QA procedures
    - Phantom placement and scanning

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 is divided into four safety zones as indicated on the attached Safety Zone Map (http://mri.brown.edu/docs/MRF-Zone_Map.pdf). These zones are labeled 1-4 and each zone represents a progressively greater level of access restriction.

Zone 1: Public areas with unrestricted access.

Zone 2: Interface between public areas and restricted areas (waiting room, changing area, behavioral testing). Visitors and volunteers do not require an escort in Zone 2.

Zone 3: Highly restricted area. All visitors and volunteers in Zone 3 *require escort by authorized personnel* to enter this zone.

Zone 4: 3T MRI Scanner Room (124A) and Equipment room (122A). 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. All volunteers and visitors must be accompanied by Level 2 or Level 3 personnel in Zone 4.

All experimental animals must be transported into and out of the magnet room through the side door. This door opens only from the inside.

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 (http://mri.brown.edu/docs/MRF-Zone_Map.pdf). 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.

* Card Key Level 1: Access to Reception and Waiting area (rm 126) from public hall.
* Card Key Level 2: Access to restricted areas including MRI Equipment Room (122A) but not including access to MRI Control Room (rm 124) or 3T Scanner Room (rm 124A).
* Card Key Level 3: Access to the 3T Control Room

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

Guidelines For Personnel And Zone Restrictions:

a. The current operator of the MRI system has full responsibility for controlling access to the MRI magnet room.

b. Any volunteer entering the magnet room must be accompanied by a Level 2 or Level 3 personnel. The ultimate responsibility to ensure MRI safety and controlling site access, remains with the on-site Level 3 individual currently in charge of the MRI system.

c. Visitors and Volunteers may only enter Zone 3 with the escort of a certified Level 1, Level 2 or Level 3 individual.

d. 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 (124A) or Equipment 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 (124A) or Equipment Room (122A).

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.

SECTION 4: MRI SYSTEM OPERATION

This section describes and defines who may operate the MRI system.

MRI system operation. 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 the Safety, Education and Training Committee. A second individual with Level 2 or above training must be present to assist a Level 3 operator during MRI system operation with human volunteers or experimental animals.

Operation by Brown-affiliated, non-MRF research personnel 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, graduate students in 'good' standing (as defined by Brown's Graduate School) and research assistants may potentially be certified to operate the MRI system unaccompanied by a Level 3 certified MRF staff member. Those wishing to become certified as Level 3 scan operators should submit a request to the MRF Associate Director for Research for consideration. Requests from postdoctoral fellows, graduate students and research assistants must have an accompanying memo from the faculty supervisor indicating the rationale of the request to train the specified individual to Level 3 competence. Upon receipt of the request, the trainee may arrange Level 3 training with the Facility Manager as outlined in Section 2. When training is complete and competence is demonstrated, Level 3 certification may be conferred by the Safety, Education and Training Committee and the MRF Medical Director. Note: The MRF Director, Associate Directors and Facility Manager reserve right to refuse permission for anyone to operate the scanner at any time, even after Level 3 certification has occurred.

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

Experimental MR software and hardware. Most researchers will use 'product' software and hardware. However, some researchers will use non-product "Works-in-Progress" (WIPs), prototype, or custom software and hardware, only with IRB approval. Use of non-product WIPs, prototype or custom hardware by non-MRF staff will also require permission from the Safety, Education and Training Committee.

Usage Logs and Compliance. All use of the MRI System must be recorded in the MRI Scan Log that is kept next to the scanner console. The Scan Log records the time of use, the scanner operator, the fact that required personnel were present and that the appropriate screening form was reviewed. The scan log will be reviewed weekly by MRF personnel for accuracy and completeness.

SECTION 5: EMERGENCY RESPONSE

This section describes 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 Procedure

In the event of a medical emergency, the first responder (MRI system operator, researcher or other individual) is responsible to call Brown Public Safety from the nearest telephone.

Campus phone - 3.4111
Non-campus phone - 863-4111
Identify the event and location (Sidney Frank Hall for Life Sciences, Room 124A).

If a research participant is within the bore of the MRI system:

1. The MRI operator/designee will engage **TABLE STOP** and manually pull the research participant out of magnet bore.
2. Free participant from coils and all immobilization devices.
3. Operator/designee will **Transfer** the research participant to a non-ferrous stretcher
4. The operator/designee will then **Remove** the research participant from the magnet room.
5. The operator/designee will **Secure the magnet room door** .The MRI system operator is responsible to ensure no one enters magnet room without proper screening for MRI safety.
6. A on-site individual certified in BCLS will **Start CPR** if necessary.
7. A research assistant or designated staff member will meet the emergency responders at the entrance to the building outside of the vestibule on the 1st 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.
8. The MRF staff or Laboratory personnel will cede responsibility to emergency responders as they enter the Wait Entry Room, Room 128, assisting the 1st responders as requested.
9. The MRF staff will file an incident report and notify appropriate University personnel.

MRI System Quench – Emergency Magnet Run-Down

A magnet quench quickly dissipates the scanner's magnetic field and may be initiated by pressing one of the two Magnet Stop buttons. A quench should **only** be initiated by authorized personnel in the event of a **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. In the event of a spontaneous 'quench' of the MRI system, follow procedure starting with Evacuation of all personnel and visitors.

1. **Start quench** by engaging 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.
2. **Evacuate** the magnet room and control room
3. **Notify Brown Public Safety**.
4. **Notify Siemens** of the quench.
5. File incident report and notify appropriate University personnel.

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 QUENCH** located in the control room or in the magnet room.
2. Follow standard evacuation procedure (see below).

Evacuation Procedure

1. The MRI system operator will lock the door to the magnet room.
2. In case of fire alarm 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.
3. All personnel are to evacuate the building through Entry Vestibule 128.
4. All personnel are to proceed to the assigned meeting area, directly across Meeting Street in front of Alumnae Hall to verify personnel accounting.
5. 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.

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 serious and unexpected adverse event involving a human research volunteer or an experimental animal.
2. The MRI system operator will file a report of the incident, co-signed by the relevant PI and laboratory member in charge of the experiments. This report will 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, Education and Training Committee.
3. 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 Office of the Dean of Medicine and Biological Sciences
   * 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)

SECTION 6: 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.

Screening Forms

Screening forms may be obtained from the MRF web site

http://mri.brown.edu/docs/

Screening Form for Volunteers 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 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 being going in the scanner must be screened with the form for Volunteers.

Prescreening and Participant Screening

Researchers are encouraged to prescreen their volunteers for MRI contraindications prior to scheduling them for scanning. Researchers will be charged for last minute cancellations. All volunteers **must** be interviewed and complete a screening form on-site prior to entering Zone 4 regardless of whether or not they have been prescreened. The screening form itself is a tool to assist the individual performing the screening in their interview with the volunteer. Screening must be done through an in-person interview and completing the screening form does not in itself constitute volunteer screening.

If 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. The MRI system operator will additionally verbally screen the volunteer prior to entering the magnet room. Females that self-report pregnancy, will be excluded from participation unless the protocol specifically has pregnancy as an inclusion criterion. **The MRI system operator is ultimately responsible for ensuring that all persons entering the magnet room have been properly screened**.

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.

Clothing

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.

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 participants

Definition: Identification of potentially abnormal finding while the research participant is undergoing an MRI procedure. The MRI system operator will contact the MRF Medical Director and provide relevant images as directed. The MRF Medical Director will contact the PI who contacts the research volunteer in the event the subject should follow up with clinician.

SECTION 7: MRF GOVERNANCE

The Brown University MRI Research Facility has established three committees for operational oversight and policy review. Current membership rosters may be found at

http://mri.brown.edu/org

Executive Committee

The MRF Executive Committee provides strategic guidance on all policy matters related to the MRF including those related to operations, financial planning and staffing. The committee meets at least twice per year to hear a report from the MRF Director and Associate Directors regarding recent usage of the facility and to discuss and to make recommendations regarding any current matters of interest. The Executive Committee has overall authority for actions of other MRF Committees through approvals and directives. Decisions of the Executive Committee occur by a 60% vote of those present at a meeting. Members can vote by prearranged proxy. Some decisions can occur via E-mail polling. The Executive Committee has a quorum of 50% attendance. Policy decisions by the Executive Committee do not supersede those instituted by the University administration.

Safety, Education and Training Committee

The Safety, Education and Training Committee (SETC) of the MRF has oversight regarding the safe operation of the 3T MRI system. The committee sets operation procedures for the MRI system; these procedures will undergo annual review, though they can be modified at any time when new safety concerns arise. Additionally, this Committee will approve training procedures for Level 1, Level 2, and Level 3 personnel to ensure proper use of equipment and implementation of general MRF policies and procedures. The Safety, Education and Training Committee and the Medical Director must agree to certify a user for independent operation of the MRI system. Additionally, the Committee approves and oversees requests for usage of the facility for educational purposes. In cases when coursework is proposed to occur in the MRF, the Committee includes faculty representatives appointed by the Graduate Counsel and the College Curriculum Council. The Committee meets in person at least annually to review safety policy and as needed for other matters.

The Safety, Education and Training Committee will receive an annual report from the MRF Associate Director of Research that summarizes violations of the MRF Standard Operating Procedures or other matters that potentially compromise the safe operation of the MRF. The committee may also receive ad hoc reports that detail violations that might require more immediate action. When considering such reports, the committee may recommend that the MRF administration implement one or more specific actions; among others these, these include:

* written warnings concerning violations that could lead to further action
* placing individuals on probationary status for specified durations, with a detailing of the rationale for the probation and the conditions under which the probationary status would cease and whether the probationary status would advance to sanctions
* demotion of training status (e.g., from Level 3 to Level 2)
* revoking operating privileges for a specific period of time.

In all cases of MRF action, the MRF administration will inform the supervisor of the involved individual about the action taken. Additionally, the MRF administration will include a synopsis of policy and procedure violations and actions taken by the MRF in official reports provided to other University entities.

Scientific Advisory Committee

The Scientific Advisory Committee reviews research protocol applications to use the resources of the MRF. Potential Principal Investigators submit a set of documents that become distributed to Committee members. The committee reviews proposals to establish whether the proposed research is feasible, has fundamental scientific merit and is consistent with the mission of the MRF. Review of proposals at this early stage can identify important issues that may need to be addressed by either the submitter(s) or by the MRF in the process of implementing the research protocol. Such issues may relate to special hardware or pulse sequence needs, biosafety concerns, staffing and scheduling concerns, among others. The Medical Director and the Associate Director for MRI physics examine each application for medical and physical safety. For proposals requesting free or subsidized scan time the Committee reviews the submission to ensure that the submitter has a reasonable plan by which to use the data to apply for external funding to be utilized at the MRF. The work of the Committee is typically done through email though it may meet in-person from time to time.

Policy Changes

Proposals to alter or amend standard operating procedure for the MRF, as reflected in this document, may originate from any interested party including the user community, the various committees described above and the University administration. After policy changes have been discussed and approval recommended by the Executive Committee, they are then subject to approval by the office of the Dean of Medicine and Biological Sciences.

GLOSSARY

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.

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.

MRI SYSTEM: Siemens 3T TIM Trio

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

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

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.

Appendices

A. MRF Application and Fee Schedule

http://mri.brown.edu/docs/MRF_Application_Form.pdf

B. Specialized Brown IRB policies for MRI-related protocols

http://research.brown.edu/pdf/MRI_submsn_policy.pdf

C. MRF Suite Safety Zone Map

http://mri.brown.edu/docs/MRF-Zone_Map.pdf

D. MRI Screening Form for Volunteers

http://mri.brown.edu/docs/MRF_Screening_Form_v2.pdf

E. Non-Volunteer Screening Form

http://mri.brown.edu/docs/MRF_Nonvolunteer_Screening_Form.pdf

F. MRI Safety Documentation Form

http://mri.brown.edu/docs/MRF_Safety_Documentation_Form.pdf