

Magnetic Resonance Research Center (MRRC) Safety Policy

1. Regulatory Requirements for the Conduct of Human Studies

- a. HIC and MRRC Approval: The MRRC Protocol Review Committee and the Yale University Human Investigations Committee (HIC) must approve all study protocols conducted within the MRRC. Investigators interested in conducting research using MRRC facilities will email research protocols to the coordinator of the MRRC Protocol Review Committee. Protocols must use HIC templates and include the form called Proposal for use of MRRC, available from the MRRC web sites (<http://mrcc.yale.edu/>).
- b. Informed Consent: Signed informed consent (original or copy) must accompany the study subject for review prior to any MR study.
- c. MRRC Safety Checklist: Subjects or their legal guardians (in the case of children or mentally retarded patients) or legally appointed decision-makers (in the case of patients who otherwise lack decision-making capacity) must fill out the MRRC safety checklist sheet prior to their study. Sheets are available from the technologists and the MRRC web sites. The completed safety sheet must accompany the study subject for review prior to the start of the study. If the subject indicates on the sheet they have a risk factor for an MR study, the study will be cancelled unless cleared by the Medical Director or MRRC Director.
- d. Controlled Drugs: Controlled substances other than those medicines included in the emergency cart will not be stored in the MRRC. Investigators must take full responsibility for tracking and recording any controlled substances they administer to subjects.
- e. Responsibility of Principal Investigator: It is the responsibility of the principal investigator and his or her research staff to ensure the availability of the signed informed consent and safety sheet and to confirm the HIC status of the study protocol. A copy of the HIC approval and end date must be presented to the MRRC scanning personnel. MRRC scanning personnel can also access the Coeus system to ensure the study is HIC approved. If the HIC approval for the protocol is expired or the informed consent is not available, the MR study will be cancelled. The principal investigator must also inform the MRRC staff whether or not a subject has received any medication in preparation for the study and must insure that appropriate medical staff is available (see section 3, subject stratification). The Yale University Human Investigations Committee (HIC) study approval letter will not be retained by the MRRC or in the MRRC site file. It is the responsibility of the Principal Investigator to maintain the HIC approval in the study file under their control

- f. Staff Training: All research personnel who work in the MRRC must undergo MR Safety Training. **No one will be permitted to go beyond the waiting room into the MR Research area unless they are trained in MR Safety (as set forth below) or they obtain clearance from the MRRC Director or the Medical Director.** Training consists of the following 4 requirements: (1) Online course and test on MR Safety, a one-time requirement; (2) MR Safety Sheet, required every two years; (3) GE safety video, a one-time requirement and (4) The MRRC Imaging Policy form, a one-time requirement. The 2 documents in items 2 and 4 can be found at <http://mrrc.yale.edu> click on Information for Users and you will see links for the MR Safety sheet and for New User Info. The safety sheet and the signed page of the MRRC Imaging Policy can be hand delivered to the Senior Administrative Assistant at the MR Research Center, TAC N153A in a sealed envelope or sent by fax to 203-785-6025. The four elements of MR Safety (online course, video, safety sheet, and new user form) will be tracked for each researcher by the Yale Training Management System (TMS).
- g. Medical Staff training: In addition to the training described above in section f., medical personnel who may have to perform emergency medical procedures must meet directly with the Medical Director of the MRRC for orientation and review of emergency procedures prior to the start of the research protocol.

2. Standard Operating Procedures for Medical Safety in the MRRC: Preventive Action

- a. The physical and mental status of each subject will be evaluated by the attending physician, principal investigator, or research staff before entering the MRRC.
- a. All subjects and research staff will undergo screening for metallic objects before entering the MRRC. If objects are found they will be removed and stored in the locked boxes in the reception area. Those with implantable metal devices will not be allowed in the area.
- b. No one is permitted to go beyond the waiting room unless the MR operator, MRRC Director or Medical Director gives clearance.
- c. Each subject or a parent or a guardian will fill in the MR safety sheet prior to participation in a MR study. Those with risk factors for MR studies, such as critically implanted magnetic objects (i.e., aneurysm clips, cardiac pacemakers etc.) will not be allowed in the magnet area unless approved by the Medical Director or MRRC Director. All subjects will be asked whether or not they have received medication in preparation for the MR study. After the study the safety sheet should be stored with the subjects consent form by the Principal Investigator.
- d. All research staff that might accompany the subject into the magnet room must undergo annual MR safety training and must also fill out the MR safety sheet every

two years (see 1f above).

- e. On the 4T and 7T systems, all subjects and ancillary research personnel must change into scrubs and pass through the ferromagnetic detector.
- f. On the 1.5T and 3T systems, all subjects must pass through the ferromagnetic detector and the investigator has the option of having subjects change into scrubs.
- g. A member of the research team must be present with every study and must be able to work in the presence of a magnetic field. The MR operator will not conduct the study alone unless the MRRC Director or the Medical Director provides an exemption. One of the two people conducting a study must be trained in Basic Cardiac Life Support (BCLS).
- h. The door to the magnet room must be kept closed at all times.
- i. All equipment necessary to conduct the study must be in place in the magnet room before the subject enters the magnet room. After the subject is positioned in the scanner, no additional equipment can be brought into the MR. The MR operator is the only person who can enter the room or give permission to enter the room. If there is an emergency, see section 4 below.
- j. No oxygen tanks can be brought to the MRRC scan rooms. The MRRC has an oxygen supply available for emergencies and for studies with subjects who require supplemental oxygen or airway suction. Exchange of tanks must happen outside the MRRC scan rooms.
- k. A study can be cancelled if there is a breach in MR safety.

Summary of documentation required by the MRRC. Provide a copy of a current HIC and end-date of the project. Provide a MR safety sheet and a signed HIC consent form each time a subject has an MR study. Ensure that all research staff undergo MR safety training. Safety training that must be done every 2 years includes taking the online MRRC safety course and filling out the MR safety sheet. In addition, each researcher must fill out the MR New User Information Form once and watch the safety video once.

3. Subject Stratification for Studies in the MRRC

Each proposed study will be evaluated by the MRRC Protocol Review Committee. The level of subject supervision required for an MR study will be based primarily on risk stratification as defined by guidelines of the Human Investigation Committee (HIC). General guidelines are listed below (also see table 1).

- a. **Level 1 (Very low risk)** studies have risk commensurate with ordinary daily life or risk encountered in the performance of routine physical or psychological examinations. Level 1 studies involve subjects who do **not** require anesthesia and who do **not** receive intravenous infusions, drug infusions, MR contrast agents, or controlled substances (intravenous or oral). Level 1 studies are monitored by the MR operator and a research person who accompanies the subject. Level 1 subjects younger than 5 years or occasional Level 1 adult subjects will also be monitored by a PA or registered nurse in addition to the research staff and MR operator. **The registered nurse, PA or APRN must be provided by the primary investigator.** Emergency medical service (911) is available.
- b. **Level 2 (Low risk)** studies carry slightly more risk than ordinary daily life. Level 2 studies involve subjects who receive oral or IV substances with no or mild potential side effects, or who have a medical condition that slightly raises their risk profile during the MR study. Low risk subjects are monitored by the MR operator, the research person, and a registered nurse or physician's assistant (PA) trained in basic cardiac life support (BCLS). A licensed physician trained in BCLS must be available by pager in the medical school or hospital during the conduct of the study. **The registered nurse, PA or APRN and the licensed physician must be provided by the primary investigator.** The physician will be paged or will call in at the start of each study to confirm availability. The study will not proceed until contact with the physician is made. Emergency medical service (911) is available.
- c. **Level 3 (Moderate risk)** studies have risk recognized as being greater than both low risk categories (Level 1 and Level 2) but less than high risk studies. There is adequate surveillance and protection to discover adverse events promptly and to keep their effects minimal. Examples of moderate risk studies include subjects who receive oral or IV substances that have low to moderate risk potential of side effects, or subjects who have a medical condition that moderately raises their risk profile. Moderate risk subjects are monitored by the MR operator, the research person, a registered nurse or physician's assistant (PA) trained in basic cardiac life support (BCLS), and a licensed physician trained in BCLS during the conduct of the study. **The registered nurse, PA or APRN and the licensed physician must be provided by the primary investigator.** Emergency medical service (911) is available.
- d. **Level 4 (High Risk)** studies have risk that carries potential harm to a subject based on the nature of the study or based on significant uncertainty about the possible occurrence or nature of the risks. Level 4 studies involve subjects who require anesthesia or receive oral or IV substances that have a risk of serious side effects or receive infusions of MR contrast agents. Subjects with previously diagnosed medical conditions that put them at risk for potential serious adverse events are included in this category. Level 4 subjects are monitored by the MR operator, the research person, and a registered nurse or physician's assistant (PA) trained in advanced cardiac life support (ACLS). A licensed physician trained in

ACLS must be on-site within the MRRC during the conduct of the study. **The registered nurse, PA, or APRN and the licensed physician must be provided by the primary investigator.** For studies involving MR contrast agents, it is sufficient to have an MD and MR operator be present for the study. For subjects receiving general anesthesia, the physician will be an anesthesiologist. For subjects receiving conscious sedation, the physician will be an anesthesiologist or a physician who is certified in conscious sedation and ACLS, and trained in airway management. Emergency medical service (911) is also available. For studies requiring intravenous contrast agents, the standard of care across Connecticut requires that a licensed physician be present when intravenous contrast is administered. It is the responsibility of the principal investigator to comply with state law and provide physician coverage. An estimated glomerular filtration rate (eGFR) must be documented for all subjects receiving intravenous contrast agents. A subject with an eGFR less than 30 ml/min/1.73m² cannot receive intravenous contrast. A subject with severe liver disease and an eGFR less than 40 ml/min/1.73m² cannot receive intravenous contrast.

Table 1. Medical Supervision for Subjects

HIC Risk Class	Level of Supervision			
	MR Operator, Research Staff	RN, PA, APRN	MD	EMS 911
Level 1 Very Low Risk	On Site	*		Available
Level 2 Low Risk	On Site	On Site BCLS	Pager	Available
Level 3 Moderate Risk	On Site	On Site BCLS	On Site BCLS	Available
Level 4 [#] High Risk	On Site	On Site ACLS	On Site ACLS	Available

* Level 1 subjects younger than 5 years or adult subjects that require more monitoring will also be accompanied by a nurse or PA. Most Level 1 subjects will be monitored by the MR operator and research staff.

For studies involving contrast, an MD and MR operator are sufficient.

- e. The MRRC purchased a fully equipped code cart from Banyan called Statkit. An automated program tracks the expiration of the medicines in the code cart.

Updated medications are mailed to the MMRC and placed in the code cart by the Medical Director or the MRRC technologists. Expired meds are placed in a shipping bag provided by Banyan and returned to Banyan.

- f. A designated individual will review weekly a checklist of safety equipment to insure that it is in working order. The equipment on the checklist includes defibrillator with paddles for adults, children and infants, sphygmomanometer with adult, child and infant cuff sizes, suction equipment with adult catheters and pediatric suction catheter sizes from 6-12, the status of the lock on the code cart, and whether oxygen and wall suction are available.
- g. An engineer on site in the MRRC will review weekly a checklist to verify that oxygen supply is available and that the compressor for wall suction is functioning. The oxygen supply and compressor will be recertified annually according to guidelines established with the company contracted to install and recertify oxygen and air suction in the MRRC.
- h. While studies of moderate risk or high risk are underway, the safety equipment can be moved to the alcove outside the scan rooms for use in the case of emergency. The safety equipment includes the code cart, IV pole, sphygmomanometer, oxygen masks, defibrillator, and suction equipment.
- i. No metallic objects may pass across the hatched safety line outside the door of each scan room.
- j. In the event of an incident or emergency, the study subject **MUST** be removed from the scan room for evaluation and treatment. Do not bring equipment into the magnet room under any circumstances.

4. **7T Safety**

- a. Access to The 7T scanner room (room with the magnet) is limited to the 7T MR operator, MR engineers and the MRRC Medical Director and appropriately screened subjects. The 7T MR operator for each study will determine whether or not other personnel involved in a particular study can enter the scanner room.
- b. Access to the 7T scanner console area is permitted only by the 7T MR operator.
- c. Equipment in the console room and scanner room will have designated locations and can be moved only by the personnel listed in 4a above. If a researcher moves equipment without permission, that researcher can lose access privileges to the 7T console room for up to 6 months. The penalty will be determined at the discretion of the research group, MRRC Director and MRRC Medical Director.

- d. Prior to entry into the 7T scanner room, all subjects who are studied on the 7T system and all ancillary research personnel must change into hospital scrubs and pass through the ferromagnetic detector. If subjects have impaired mobility, they do not need to change if their garments are determined to be MR safe by the 7T operator.
- e. All personnel involved in MR research must meet the safety requirements detailed in section 1f of this document.

5. Contrast Agents

- a. For studies requiring intravenous contrast agents, the standard of care across Connecticut requires that a physician be present when intravenous contrast is administered. It is the responsibility of the principal investigator to comply with state law and provide physician coverage.
- b. An estimated glomerular filtration rate (eGFR) must be documented in the past 30 days for all subjects receiving intravenous contrast agents. A subject with an eGFR less than 30 ml/min/1.73m² cannot receive intravenous contrast. A subject with severe liver disease and an eGFR less than 40 ml/min/1.73m² cannot receive intravenous contrast.

6. Medical Emergency Procedures for Human MR Studies

- a. Call 911 (this is the emergency number for Yale University) to request emergency medical service (EMS).
- b. It is very important to identify the location of the emergency, which is the Anlyan Center (TAC) on the **corner of Congress and Howard Avenue**. This is the back entrance to TAC, not the front entrance.
- c. Call Yale security at (203) 785-5555 and tell them EMS will be directed to the back entrance of the MRRC at the corner of Congress and Howard Avenue. Security cannot leave the desk during weekday work hours but will be able to assist in directing EMS after 7pm and on weekends.
- d. Move the subject from the scan room to the scanner console area or to the Medical Care room and remain with the subject until EMS arrives. An emergency stretcher with a transfer board is available to move the subject out of the scan room.
- e. If indicated, basic cardiac life support or medical therapy can be administered when the subject is moved out of the scan room.
- f. Do not bring equipment into the scan room.

- g. If there are 2 research personnel, one person stays with the subject and the other will direct EMS to the subject in the MRRC.
- h. If you are scanning alone and there are no other people in the area to assist you, you will have to leave the subject and direct EMS to the subject in the MRRC. The front-desk security can assist in directing EMS if it is late at night or on weekends.
- i. To meet and direct EMS to the subject, walk through the doors on the west side of the imaging room (the doors by the 3.0 T and 4.0 T magnets). Then, go through two more sets of doors to reach the outside. Turn right and walk up the ramp to a gated fence. Open the gated fence and have EMS come in the building and evaluate the subject.
- j. Call or page the principal investigator for the study and call the physician collaborator if your study has one.
- k. After the emergency, report the adverse event to the HIC, as well as to YNHH Legal and Risk Services Department.

7. Emergency Procedure for Power Failure

- a. Remove subject from scanner table.
- b. Call Security Emergency 785-555 or Facility Customer Service 785-4620 or Facility Urgent Repairs 432-6888.
- c. Report location.
- d. Do not hang up until instructed to do so.
- e. Request a crew from OEHA for immediate assistance.
- f. Follow instructions of OEHA or emergency personnel.
- g. If advised to do so or if power failure is expected to last for an extended period of time evacuate to your department's mustering area. Await further instructions.
- h. Security will report all incidents to Security Emergency at 785-5555.

8. Emergency Procedure in case of a Magnet Quench

- a. Do not panic.

- b. Understand that a quench does not mean that the magnet has lost all of its magnetism.
- c. Make sure no metal objects enter the scan room.
- d. Use the intercom to tell subject to stay calm and that someone will be in immediately to help him or her.
- e. Prop open the door between the magnet scanner room and the console.
- f. Enter the room, help the subject off the scanner table and exit the scan room.
- g. Evacuate all personnel from the area.
- h. Proceed to your department's meeting place, which is the CORNER of CONGRESS and CEDAR STREETS.
- i. Call Yale Security: 785-5555.
- j. Call Local Building Operations Manager for MRRC, at 785-6198 or 203-988-2294.
- k. Do not re-enter the scanning area until emergency personnel declare that it is safe.

9. Corrective Action:

- a. MRRC personnel or PI will report adverse events to the MRRC Protocol Review Committee and to YNHH Legal and Risk Services Department.
- b. The Committee will review the event.
- c. The Committee will initiate any necessary changes in SOP as a result of the event.
- d. The MRRC will notify principal investigators and vendors about the event and any changes in procedure that resulted.
- e. If the new SOP leads to new training requirements then time-lines will be established to phase in the procedure if conditions allow, or studies will be halted until they conform with the new SOP if the SOP concerns a safety issue.