Magnetic Resonance Research Center (MRRC) Safety Policy

1. Regulatory Requirements for the Conduct of Human Studies

a. IRB and MRRC Approval: The MRRC Protocol Review Committee and the Yale University Human Research Protection Program (HRPP) must approve all study protocols conducted within the MRRC. Studies using YCCI resources will require approval from the YCCI General Advisory Committee (GAC). Investigators interested in using MRRC facilities will fill out the form called Proposal for use of MRRC Resources and upload it as a Supporting Document in IRES IRB. When studies are submitted in IRES IRB, the Human Research Protection Program (HRPP) staff will request review from MRRC Protocol Review Committee, by notifying Meko Owens-Ward. The MRRC Protocol Review Committee will review the protocol and submit their findings in IRES IRB. The study will not proceed to the IRB until MRRC approval is granted.

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 guardian 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 insure 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 provided to the MRRC where it will be kept on file. 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).

f. Staff Training: All research personnel who work in the MRRC must undergo MR Safety Training. **No one will be given access or permitted to go beyond the waiting room into the MRRC Research area unless they are trained in MR Safety or they obtain clearance from the MRRC Director or the Medical Director.** Training consists of the following 4 requirements: (1) Online course and quiz on MR safety, one-time requirement; (2) GE safety video, a one-time requirement; (3) Read and attest to the MRRC Imaging Policy form, a one-time requirement, and; (4) MR safety questionnaire, required every 2 years. The 2 links for this training can be found at http://mrrc.yale.edu and will be tracked for each researcher by Workday Learning (WDL). All research personnel who join an ongoing project must also be trained in MR safety.

g. Medical Staff training: In addition to the training described above in section f., medical personnel who may have to perform emergency medical procedures need to meet directly with the Medical Director of the MRRC for orientation and review of emergency procedures.

2. **Standard Operating Procedures for Medical Safety in the MRRC**

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.

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 each year (see 1f above).

e. On the 4T, all subjects and ancillary research personnel must change into scrubs and pass through the ferromagnetic detector.

f. On the 3T Prisma and 3T Vida 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. The MRRC has as an oxygen supply available for emergencies and for studies with subjects who require supplemental oxygen or airway suction.

k. A study can be cancelled if there is a breech 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. Insure 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.

Adult Studies (See Table 1)

a. ***Minimal risk*** is risk commensurate with ordinary daily life or with risks encountered in the performance of routine physical or psychological

examinations. Minimal risk studies involve adult subjects who do **not** require anesthesia and who do **not** receive intravenous infusions, drug infusions, MR contrast agents, or restricted drugs (intravenous or oral). Minimal risk subjects are monitored by the MR operator and a research person who accompanies the subject. Emergency medical service (911) is available.

b. ***Moderate risk*** is risk recognized as being greater than minimal risk but less than high risk. There is adequate surveillance and protection to discover adverse events promptly and to keep their effects minimal. Examples of moderate risk studies include adults who receive intravenous infusions of MR contrast agents, glucose infusions, insulin infusions, infusion of stable isotopes, nicotine patches, or medication with a low risk of serious side effects. Moderate 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 staff physician must be on site within the MRRC and available by pager. **The registered nurse or PA and the licensed staff physician must be provided by the primary investigator.** The emergency medical service (911) can also be called in the event of an emergency. For studies requiring intravenous contrast agents, the standard of care across Connecticut requires that a physician be present then intravenous contrast is administered. It is the responsibility of the principal investigator to comply with state law and provide physician coverage. All subjects receiving intravenous contrast agents must have blood work documenting the levels of blood urea nitrogen (Bun), creatinine, and the estimated glomular filtration rate (eGFR). A subject with an eGFR less than 30 ml/min/1.73m^2 cannot receive intravenous contrast.

c. ***High risk*** is 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. High-risk studies involve adult subjects who require anesthesia or receive drugs that have a risk of serious side effects. Subjects with previously diagnosed medical conditions that put them at risk for potential adverse events are included in this category. High-risk 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 staff physician designated by the primary investigator must be on-site within the MRRC during the conduct of the study. **The registered nurse or PA and licensed staff physician must be provided by the primary investigator.** For subjects receiving anesthesia, the physician will be an anesthesiologist or a physician certified in conscious sedation. Emergency medical service (911) is also available.

Table 1. Medical Supervision for Adult Subjects

HIC Risk Class	Level of Supervision			
	MR Operator, Research Staff	RN, PA	MD	EMS 911
Minimal Risk	On Site			Available
Moderate Risk	On Site	On Site BCLS	In TAC	Available
High Risk	On Site	On Site ACLS	On Site ACLS	Available

Pediatric Studies (See Table 2)

d. ***Minimal risk*** is risk commensurate with ordinary daily life or with risks encountered in the performance of routine physical or psychological examinations. Minimal risk studies involve healthy pediatric subjects who do **not** require anesthesia and who do **not** receive intravenous infusions, drug infusions, MR contrast agents, or restricted drugs (intravenous or oral). Subjects older than 7 years are monitored by the MR operator and a research person. Subjects younger than 7 years are monitored by the MR operator and a registered nurse (RN), a physician's assistant (PA), or research associate (RA) trained in basic cardiac life support (BCLS). The primary investigator must provide the personnel necessary to safely staff the study. Emergency medical service (911) is available.

e. ***Moderate risk*** is risk recognized as being greater than minimal risk but less than high risk. There is adequate surveillance and protection to discover adverse events promptly and to keep their effects minimal. Examples of moderate risk studies include children who receive intravenous infusions of MR contrast agents, glucose infusions, insulin infusions, infusion of stable isotopes and nicotine patches. Moderate risk subjects are monitored by the MR operator, a research person, and a registered nurse or physician's assistant (PA) trained in basic cardiac life support (BCLS). A licensed staff physician designated by the primary investigator must be on-site within the MRRC during the conduct of the study. **The registered nurse or PA and licensed staff physician must be provided by the primary investigator.** Emergency medical service (911) can also be called in the event of an emergency. Note that a healthy child who receives an MR contrast agent will be stratified into the moderate risk category. For studies requiring intravenous contrast agents, the standard of care across Connecticut requires that a physician be present then intravenous contrast is administered. It is the responsibility of the principal investigator to comply with state law and provide physician coverage. All subjects receiving intravenous contrast agents must have blood work documenting the levels of blood urea nitrogen (Bun), creatinine, and the estimated glomular filtration rate (eGFR). A subject with an eGFR less than 30 ml/min/1.73m^2 cannot receive intravenous contrast.

f. ***High risk*** is 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. High risk studies involve pediatric subjects who require anesthesia, receive restricted drugs (oral or intravenous), or receive drugs that have a risk of serious side effects. Pediatric subjects with previously diagnosed medical conditions that put them at risk for potential adverse events are included in this category (e.g. fetal stroke). High risk subjects are monitored by the MR operator, a research person, and a registered nurse or physician assistant trained in advanced cardiac life support (ACLS). A licensed staff physician designated by the primary investigator must be on-site within the MRRC during the conduct of the study. **The registered nurse or PA and licensed staff**

physician must be provided by the primary investigator. For subjects receiving anesthesia, the physician will be an anesthesiologist or a physician certified in conscious sedation. Emergency medical service (911) is also available.

Table 1. Medical Supervision for Pediatric Subjects

HIC Risk Class	Level of Supervision			
	MR Operator, Research Staff	RN, PA, RA	MD	EMS 911
Minimal Risk	On Site	On site BCLS*		Available
Moderate Risk	On Site	On Site BCLS	In TAC	Available
High Risk	On Site	On Site ACLS	On Site ACLS	Available

* for children younger than 7 years.

g. Yale-New Haven Hospital will maintain the adult and pediatric code cart medicine and supplies. After each use of the code cart, the MR operator will call the pharmacy to restock the cart and to insure it is in working order.

h. 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.

i. 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.

j. 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.

k. No metallic objects may pass across the hatched safety line outside the door of each scan room.

l. 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.

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5. **Contrast Agents**

a. For studies requiring intravenous contrast agents, the standard of care across Connecticut requires that a physician be present then intravenous contrast is administered. It is the responsibility of the principal investigator to comply with state law and provide physician coverage.

b. All subjects receiving intravenous contrast agents must have blood work documenting the levels of blood urea nitrogen (Bun), creatinine, and the estimated glomerular filtration rate (eGFR). A subject with an eGFR less than 30 ml/min/1.73m^2 cannot receive intravenous contrast.

6. **Emergency Procedures for Human 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 MRRC 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 IRB.