# Advanced MRI Center (AMRIC)

## Policies and Procedures

AMRIC Oversight Committee
University of Massachusetts Medical School
Worcester, Massachusetts 06155

Initial Implementation: May 2011
Revision 1, Addition of Appendix G approved September 27, 2011
Revision 2, Updated committee personnel, Revised Appendix C approved on July 21, 2015

# AMRIC Policies

## Purpose

The purpose of the AMRIC Policies and Procedures is to maintain safe laboratory practice, during research procedures at the AMRIC facility of UMMS. It has been reported by others, that MR related injuries, fatalities, and equipment damage were the apparent result of failure to follow established safety guidelines. For the purpose of maintaining safe MRI practices, recommendations from the ***ACR Guidance Document for Safe MR Practices: 2007*** are used. In addition to safety policies, this document describes standard operating procedures of the AMRIC. Because MRI technology continues to progress, this is a living document that will be updated as needed.

## Definitions

AMRIC Executive Committee

The AMRIC Executive Committee is a recognized committee by the Department of Radiology, University of Massachusetts Medical School. Members are appointed by the Chair of the Department of Radiology to five-year term that is renewable. The Executive Committee is responsible for appointing members into the AMRIC Oversight Committee, setting the agenda for the AMRIC Oversight Committee meetings, reviewing and enforcing the recommendations of the AMRIC Oversight Committee, determining the policies of AMRIC and appointing the personnel of AMRIC. This committee meets on a monthly basis.

AMRIC Oversight Committee

The AMRIC Oversight Committee is a recognized committee by the Department of Radiology, University of Massachusetts Medical School. Members are appointed for a three-year term by the AMRIC Executive Committee. The primary function of this committee is to review and recommend strategic acquisitions to the Executive Committee, assist with research proposal reviews, and review policy violations and report corrective action recommendations to the Executive Committee. Annually, a program review will be performed by the Oversight Committee to set strategic goals and review policies for adoption. The Oversight Committee will meet quarterly.

| Executive Committee | Email | Phone |
|---|---|---|
| **Chair: Michael King, PhD** | michael.King@umassmed.edu | 2-4255 |
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Shaokuan Zheng, Ph.D., is the primary contact for equipment related questions and concerns and for MRI safety training.

MRI Research User

The MRI Research User ("Researcher"), is a Principal Investigator (PI) who has an IRB or IACUC approved protocol and utilizes the AMRIC MRI scanner for research purposes and / or a student, staff member or laboratory assistant for whom the PI is responsible.

Research Participant

A research participant ("Participant") is a human subject who is placed into the bore of the MRI scanner for research purposes.

MRI Scanner Operator

The MRI scanner operator ("Operator") is a researcher or AMRIC employee, has completed the MRI safety training and is specially trained in the operation of the AMRIC scanner. There are two levels of scanner operators:

- Operators who are allowed to operate the scanner for phantom and / or animal studies
- Operators who are allowed to operate the scanner for human research participant studies

It should be noted that the trained AMRIC MRI scanner operators have authority by the AMRIC Oversight Committee to stop any procedure that they deem exceeds safe practices.

Individual

For the purposes of this document, "Individual" is a Researcher, Operator or any personnel from AMRIC or a PI's lab that will assist with studies at AMRIC.

## Policies

Safety Training

1. Any Individual working in a magnetic environment must complete the required MRI Safety Training prior to working in AMRIC.
2. It is each PI's responsibility to arrange for personnel to be trained for MRI safety, to make sure that the PI's study and all of the PI's personnel follow all the policies at UMMS, and to make sure that the PI and the PI's personnel receive annual health clearance. **The PI and his or her group members who wish to enter the scanner room or console area must finish safety training before conducting any scans.**
3. **MRI Safety Training must be renewed annually, each February**.

Standard of Practice at AMRIC

*IRB/IACUC Protocols and AMRIC Approval*

1. Before conducting any scans, the PI must have an approved IRB protocol for human studies, or an approved IACUC protocol for animal studies, on file with the AMRIC prior to scheduling scanner time.
2. Researchers must receive approval via the electronic "AMRIC Application Form" (**Appendix A**) from the AMRIC.
3. Only Researchers with approved AMRIC Application form will be allowed to schedule scanner time at AMRIC.

*Individuals*

1. The PI or her/his representative must be present for all scans.
2. Individuals working within the magnetic environment must be screened for safety risks prior to entering the magnetic field. This includes Individuals who may be accompanying a Participant. THERE ARE NO EXCEPTIONS TO THIS POLICY.
3. Two MRI safety trained Individuals should be on site when any MRI study is being performed.
4. Two MRI safety trained Individuals must be on site when a Participant is being scanned. NOTE: the Participant may not count as one of the MRI safety trained Individuals.
5. When a Participant is being scanned, it is required that an MRI safety trained Individual with current documentation as to valid American Heart Association or equivalent cardiopulmonary resuscitation (CPR) training is present. To schedule training at UMASS in Basic Life Support, please see schedule at: http://www.umassmed.edu/cme/courses/bls/schedule.aspx?linkidentifier=id&itemid=75490

6. Individuals using the MRI system for human studies must be included on an approved IRB protocol prior to scanning human research participants.
7. Individuals using the MRI system for animal studies must be included on an approved IACUC protocol prior to scanning any animal models.
8. Individuals using the MRI system for non-human or non-animal studies must notify the AMRIC Oversight Committee of their work and must have an approved MRI Application Form.
9. Individuals who are or may be pregnant are not allowed to remain in the MR scanner room while the RF and gradients are operating.

*Research Participant*

1. When Participants are being scanned, the PI or the PI's representative must remain with the subject **at all times**, must make sure that the subject changes clothes in a locked changing room, and must wait outside of the changing room in case of emergency. THERE ARE NO EXCEPTIONS TO THIS POLICY.
2. Participants in MRI studies must be screened (**Appendix B**) for safety risks prior to entering the magnetic field. THERE ARE NO EXCEPTIONS TO THIS POLICY. It is strongly recommended that all Participants are questioned during the recruitment phase and prior to scheduling scanner time for metal implants, and other contraindications for MRI – this will save a lot of time and effort before paperwork is initiated.
3. Participants in MRI studies must be treated within institutional, local and federal guidelines and regulations.
4. Implants, devices and other objects within or on Participants or other Individuals intending on entering the magnetic environment must be investigated by the manufacturer label and this investigation must be documented prior to the Individual or Participants entering the scanner magnet room.
5. Manufacturer documentation which includes the FDA approval must be obtained to ensure safety of implants, devices or other objects at 3.0T.
6. Individuals who have Vagal Nerve Stimulation (VNS) implants are NOT safe to participate in a functional MRI (fMRI) study due to the rapid gradient switching required for Echo Planar Imaging (EPI) utilized in fMRI.
7. Individuals and Participants with suspected metallic ocular injury must be investigated and if necessary, cleared by a medical doctor before entering the magnetic environment or participating in an MRI study. Individuals and Participants with suspected metallic injury must be excluded from the MRI environment or study unless cleared by a radiographic exam.
8. Participants must be evaluated for medical status that would indicate a safety risk and or prevent a successful MRI study.
9. The Participant must be given an emergency squeeze ball with instructions for use by the researcher or the scanner operator.

10. Researchers must interview research participants identified during pre-screening as having tattoos and proceed accordingly.
11. Researchers must interview research participants identified during pre-screening as having medication patches and contact their physician or exclude the individual from the study. Researchers may not remove medication patches prescribed by physicians.
12. It is the PI's responsibility to verify that images from all Participants scanned at the AMRIC will be read by a radiologist to check for incidental findings (**Appendix C**). In exchange for reading scans, radiologists will receive a fee and free scanning time.
13. To allow the required number of air exchanges, a minimum of one hour must pass following any animal scans before human scanning can take place.
14. Individuals involved with scanning Participants must be familiarized and adhere to the Advanced MRI Center Code Policy (**Appendix D**).

*MRI Scanner Operator*

1. Operators must be trained as evidenced by signed documentation.
2. Operator must verbally monitor the Participant throughout the procedure.
3. Operators have the authority to stop MRI procedures that are deemed by them to be unsafe.
4. Researchers with proper training, and were approved by the AMRIC to run their own experiment, please adhere to the policies in **Appendix E**.

*Emergency or Illness*

1. An Individual or Participant who becomes ill or injured must be removed, from the magnetic environment, immediately by the Researcher or Operator.
2. If an Individual or Participant becomes ill or injured, the institutional policies for the scanner location must be followed.
3. If there is a Magnet Emergency, institutional policies for that specific scanner location must be followed.
4. The Researcher must report any emergency incident to the AMRIC Oversight Committee.

*Equipment*

1. Any equipment to be used within the magnet room must be approved by the AMRIC Oversight Committee designee.
2. All material and equipment must be tested for ferromagnetic properties with a hand held magnet outside of the fringe field before being brought within the magnetic field inside the scanner room.

**Background:** Due to an apparently small but serious risk of Nephrogenic Systemic Fibrosis (NSF) in individuals with severely compromised kidney function, the FDA issued an updated safety advisory regarding gadolinium contrast agents (May 2007). The AMRIC Oversight Committee recognizes that Participants may be less likely to receive clinical benefit from MRI than patients for whom it is clinically indicated. Therefore, stricter standards of safety are appropriate for Participants than clinical patients. Researchers may employ more cautious standards than these. Applications indicating Gadolinium will be used in the study will be reviewed by the full committee for approval.

Policy for research studies using gadolinium-based contrast agents in Magnetic Resonance Imaging (MRI):

1. Pregnant women should not receive gadolinium contrast agents in research studies.
2. For patients who have had a prior reaction to contrast agents may not be Participants.
3. If contrast is to be administered, informed consent must include a statement about potential for contrast reaction, including potentially fatal anaphylaxis. PI must be prepared to treat contrast reactions. Additionally, test flush must be performed to ensure IV access and catheter patency.
4. For *adult* Participants with known GFR (Glomerular Filtration Rate) values:
    a. If the GFR value obtained within 6 weeks of the date of the research scan is ≥90 mL/min/1.73m2 (normal kidney function), then MRI scanning with any FDA approved gadolinium contrast agent at FDA recommended adult dose range is permitted. Doses greater than the FDA recommendation would require specific approval by the AMRIC Oversight Committee.
    b. If the GFR value obtained within 6 weeks of the date of the research scan is between 60 and 89 (mild kidney dysfunction), then MRI scanning with an FDA approved gadolinium contrast agent other than Omniscan is permitted at FDA recommended adult dose range. Doses greater than the FDA recommendation would require specific approval by the AMRIC Oversight Committee.
    c. If the GFR value obtained within 6 weeks of the date of the research scan is <60 (moderate to severe kidney dysfunction), a repeat GFR should be done within 4 weeks of the scan. If the GFR remains <60, then gadolinium contrast agents may not be administered without specific justification of proposed dose range and added risk of NSF by the Principal Investigator, and approval by the AMRIC Oversight Committee.
    d. If GFR value obtained within 4 weeks of the date of research is <30 (severe to very severe kidney dysfunction or end stage renal failure (ESRF) with or without dialysis) then gadolinium contrast agents may not be administered.
5. For *adult* Participants with unknown GFR values: Based on population studies of renal disease, GFR values are required before gadolinium infusion for any Participants with a history of:

a. Renal disease (including solitary kidney, renal transplant, renal tumor)
b. Over age over 55.
c. Diabetes – by self-report, on inquiry.
d. Hypertension – by self report and / or current measurement.
e. Note: If the participant reports a history of proteinuria or chronic Non-Steroidal Anti-Inflammatory Drug (NSAID) use, GFR values may be obtained at the discretion of the PI and/or medical director.
f. Note: A history of severe hepatic disease, liver transplant or pending liver transplant. GFR assessment as near as possible to administration of Gadolinium.

6. No Participant should receive a cumulative dose of gadolinium contrast agent over a 48 hour period that exceeds the FDA recommended dose range.

*Static Magnetic Field*

1. Only properly pre-screened Individuals and Participants are allowed in the magnetic environment of the MR scanner room THERE ARE NO EXCEPTIONS TO THIS POLICY.
2. Only equipment and accessories approved by the AMRIC Oversight Committee are allowed to enter the magnetic environment of the MR scanner room.
3. Any incident or near incident of a projectile accident must be reported to the AMRIC Oversight Committee.

*Radio Frequency (RF) Electromagnetic Fields*

1. Only properly trained Individuals should operate devices and monitoring equipment in the magnetic environment.
2. RF pulse timing sequences that exceed FDA SAR limits must not be used.
3. Only electrically conductive devices, equipment, accessories and materials that have been thoroughly tested by AMRIC personnel and determined to be safe for MR procedures are allowed.
4. Manufacturer recommendations for safe use of all devices must be followed.
5. All non-essential electrically conductive materials must be removed from the MR system bore, including unused RF coils, cables and wires prior to scanning.

*Time Varying Magnetic Fields: Gradients*

1. Potential Nerve Stimulation
   a. Participants must be instructed to not clasp their hands or in any other way form a closed loop with their extremities to reduce or avoid peripheral nerve stimulation (PNS).
   b. Phase and Frequency encoding directions must be selected carefully by the scanner operator to avoid peripheral nerve stimulation.
   c. Researchers must continuously monitor Participants being scanned in a study and stop scanning immediately if any peripheral nerve stimulation is reported or suspected, and correct the situation before proceeding.

d. Individuals who have Vagal Nerve Stimulation (VNS) implants are NOT safe to participate in a functional MRI (fMRI) study due to the rapid gradient switching required for Echo Planar Imaging (EPI) utilized in fMRI.

7. Acoustic Noise
   a. Participants must be supplied with hearing protection to meet the OSHA guidelines; either the foam ear plugs and/or a head set system.
   b. Any Researcher or Individual who remains in the scanner room during data acquisition must wear hearing protection.
   c. The intercom and auditory stimulus equipment must be adjusted to not exceed safe dB levels for the Participant.

*Infection Control*

1. The scanning table and any other surfaces that have come in contact with the Participant must be cleaned and the linens changed BEFORE placing another Participant on the scanning table.
2. The scanning table, coil and all other surfaces that may have come in contact with an animal need to be cleaned following the completion of the study.
3. Gloves must be removed and disposed of properly BEFORE touching common areas such as scanner keyboard, log books, light switches, counter surfaces and other objects.
4. Surfaces touched with gloves must be cleaned properly before leaving the area.
5. All biohazard material must be disposed of according to regulations.
6. No food or drinks of any kind are allowed in the console area.
7. Contacting any doorknobs or console-area equipment (including the keyboard and microphone) with gloves used in animal or human procedures is strictly prohibited. Also, Individuals must wash their hands following animal or human procedures prior to touching console-area equipment.

*Reporting*

1. Injuries to Individuals or a Participant must be reported to the Principal Investigator (PI) and the AMRIC Oversight Committee within 24 hours.
2. Any incident or near incident of a projectile accident must be reported to the AMRIC Oversight Committee by the scanner operator or researcher involved and AMRIC MR physicist.
3. Equipment damage and/or failures must be reported to the AMRIC MR physicist.
4. Facility safety breaches must be reported by the Operator and AMRIC MR physicist to the MRI Oversight Committee.

# AMRIC Standard Operating Procedures

The use of Magnetic Resonance Imaging (MRI) presents known safety hazards. Policies and Standard Operating Procedures have been developed so that employees, researchers, students, colleagues, study participants, and associated equipment remain safe in the magnetic environment. All personnel working within the magnetic environment are required to complete MRI safety training.

UMMS employees and support staff assigned to work in the MRI area(s) are required to adhere to the MRI Policies and Standard Operating Procedures.

## Safe Laboratory Practice

To maintain safe laboratory practice, at least two MRI Safety Trained Individuals, besides the Participant being scanned, must be in the immediate area at all times during human experiment. That is, the Operator of the scanner and another Individual who has completed MRI safety training. When a Participant is scanned, at least one Individual must have current cardiopulmonary resuscitation (CPR) training as evidenced by a signed document and be present. For animal and phantom studies two MRI safety trained Individuals should be on site. At least one UMMS employee, student or faculty member must be present for all MRI scanning. This applies to all scanning hours including the evenings and weekends.

## Safety Training

1. Safety Training for all MRI Researchers is mandated by the AMRIC Oversight Committee and has evolved to include a three step program. Requests for MRI Safety Training should be addressed to Shaokuan Zheng: Shaokuan.Zheng@umassmed.edu
2. A renewal of MRI safety training is required annually.

## MRI Safety Screening

**Background:** The most common breaches of MRI safety occur due to an object being attracted to the Static Magnetic Field. An individual may be struck, injured or trapped against the magnet by the object. Equipment may be damaged by slamming into the magnet or being struck by another object that is accelerating rapidly due to the strong attraction of the magnetic field.

*Individuals* must be aware of which objects and devices are safe to move into the static magnetic field. Each Individual and/ or Participant must be checked for safety or pre-screened prior to entering the magnetic environment of the scanner room. A standardized form is used for evaluating the safety of an individual BEFORE that individual is permitted within the magnetic environment. MRI Safety Screening Training is a segment of the requirement for MRI researchers.

*All equipment* used for research MRI studies, including projectors and stimulus producing apparatus, must be tested for MRI safety BEFORE entering the magnetic field. MRI safe equipment is developed for specific magnetic field strengths and MRI system configurations. Equipment that may operate safely within a magnet room is NOT necessarily safe to operate in another magnet room even if the magnets are the same static field strength. Routine inspection and maintenance of equipment must be performed. Broken or malfunctioning equipment must be identified and reported to the AMRIC MR physicist. NOTE: IT IS THE PI'S RESPONSIBILITY TO ENSURE MR SAFETY AND COMPATIBILITY OF ALL EQUIPMENT THAT IS BROUGHT INTO THE SCANNER ROOM.

## Emergency Safety Procedures

In an emergency, orderly and proper procedures ensure the safety of Individuals, Researchers and the Participant. The first priority is to remove Participants or Individuals from the magnetic environment. Emergency contact information is posted at the scanner console.

Medical Emergency

1. If a Participant or other Individual with a medical emergency of illness or injury, the individual or research participant must be assisted out of the magnet room.
2. Then a call for assistance: 12345.

Emergency Stop

1. If there is an emergency such as an equipment failure that could cause injury (i.e., sparking of equipment or a fire) the Operator or designee should immediately perform an emergency stop.

Magnet Emergency

1. If an Individual or Participant is restrained or pinned by a ferrous object to the magnet: Assess if the situation is life threatening, if YES an emergency rundown to quench magnet can be performed by an authorized person.
2. If an Individual or Participant is restrained by a ferrous object to the magnet and is NOT in a life threatening situation, call for assistance to determine the optimal way of releasing the Individual or Participant from the magnetic field. If a quench is necessary proceed as above.
3. Report the incident as an accident and call for assistance to ensure ferrous object is removed from the field properly.

Emergency Quench

1. A quench includes the rapid release of cryogens and results in the loss or significant decrease of the magnetic field. A quench should ONLY be performed by authorized personnel in dire emergency that involves a serious personal injury or life threatening situation.
2. Note: in extraordinary circumstances such as an earthquake or explosion, resulting in an uncontrolled quench, the oxygen level in the magnet room may significantly decrease possibly making breathing difficult.

NOTE: ALL ABOVE EMERGENCIES MUST BE REPORTED TO THE AMRIC OVERSIGHT COMMITTEE WITHIN 24 HOURS OF EVENT.

Post MRI Scanning Procedures

The AMRIC scanner is utilized by a variety of researchers. It is important that all MRI users ensure the facility and equipment are maintained in good working order. Upon completion of the MRI study the researcher must ensure that all equipment is restored to normal operation. If there is a problem with specific equipment, it must be reported to the AMRIC. Report to the MR physicist if a supply item is becoming low in quantity especially if the last, or near last of an item is used.

No one is allowed to delete anything from the host computer, except for AMRIC's MR physicist.

Researchers will ensure that coils, shim files, configuration files, and all computers are returned to standard usage. All accessories and / or devices are to be turned off properly, cords and cables wound, and returned to their designated storage area.

It is the responsibility of the PI and his or her group to process and analyze the image data.

Reporting Requirements

*Accidents, Injuries and Incidents*

1. Any accidents causing injury to an Individual or Participant must be reported to the MRI Oversight Committee by the researcher conducting the study and MR physicist within 24 hours of the incident. In case of an accident or injury when the principal investigator (PI) is not present, the researcher present must report to the PI. If an accident or injury occurs that is not related to an MRI study, then the scanner Operator or Individual on site who is responsible and MR physicist should report to the MRI Oversight Committee.
2. Besides reporting to the MRI Oversight Committee, the accident, injury or incident may need to be reported to the UMMS: Public Safety; Institutional Review Board; and / or the Institutional Animal Care and Use Committee.

*Equipment Damage or Failure*

1. Malfunctions of equipment due to breakage or failure may present a safety risk to individuals and research participants. Damage or failure of equipment needs to be addressed immediately so that repairs or replacements can be made. Equipment problems are reported to the AMRIC MR physicist.
2. AMRIC physicist will address equipment issues, obtaining assistance if necessary. Failures that prevent normal operation or a safety risk are to be reported to the MRI Oversight Committee.

*Facility Safety Breach*

1. A facility safety breach presents a risk to Individuals, Researchers and Participants. Examples of a facility safety breach are failed access points allowing non-trained or non-escorted individuals into the magnetic environment. Open access to the magnetic environment must be addressed immediately to prevent serious injury to individuals or equipment. Other potential safety breaches include: flooding, electrical hazards and obvious structural faults. Individuals and Researchers should report any breaches to the AMRIC physicist immediately. AMRIC will report the safety breach to the appropriate facility officer and to the MRI Oversight Committee as soon as reasonably possible.

Scheduling Scanner Time

1. Check the online scheduling system for available times: http://inside.umassmed.edu/calendar_month.aspx?id=49120

   Then, contact the subject to confirm if he or she is available for a particular time. If the subject would like that time, please fill out the scheduling form **(See Appendix F)** for setting up your experiment. **Next, complete the pre-scanning safety-screening requirements (See Appendix B).** If you need to cancel a scheduled experiment, please provide at least 24-hours notice prior to your scheduled start time. If 24-hour notice is not provided, a cancellation fee equal to 20% of the fee for your scheduled time will be charged to you. If no notice of cancellation is provided, a fee equal to 100% of the scheduled will be charged. Be sure to schedule enough time to cover all needed set-up time and post-experiment -take-down time (e.g., patch loading and unloading). Preparation time in the console area and scanner room will be charged the standard fee rate.
2. Steps for scheduling scanner time:

   *Human Experiment:*

   a. MRI scheduling form and IRB protocol is approved and submitted to AMRIC

b. Prior to arriving to the center, the PI or PI's representative interviews the subject for MR safety. Specifically, if the subject has any implants, the date implanted, type, manufacturer, and detailed information (model number) of the implant should be received in writing and forwarded to the AMRIC.
c. Participant arrives to AMRIC 15 minutes before schedule time and is screened for MR safety.
d. PI or Researcher scans Participant. Participant images are sent to clinical PACS by MR Physicist.
e. MR physicist will register the subject and the subject will be assigned a DT account number.
f. Once the subject is assigned a DT account number, MR physicist logs into RIS-IC (Imagecast) and creates Participant's exam with Participant's information from registration.
g. With exam and images now attached, the study will fall into the designated study filter for the Radiologist to read.
h. The MR physicist will notify the radiologist to read the scans and the radiologist will notify PIs the result after reading the scans. It is the PI's responsibility to verify that the radiologist read the scans and to read the report on those readings from the radiologist.

*Animal Experiment:*

a. MRI scheduling form and IACUC protocol is approved and submitted to AMRIC
b. PI or Researcher arrives to AMRIC 15 minutes before schedule time and the animals and all related stuff are screened for MR safety.
c. PI or Researcher scans the animals.
d. PI or Researcher takes the animals out of the scanner room.
e. PI or Researcher cleans the scanner room.

# APPENDIX A: AMRIC Application Forms

## Animal MRI Research Application Form

**PROJECT TITLE:**

**PRINCIPAL INVESTIGATOR**:
*Names Title Department Phone e-mail*

**STUDY CONTACTS**: (Principal Research Fellows, Study Coordinators, etc.)
*Names Title Department Phone e-mail*

**STUDY SCHEDULER:**
*Names Title Department Phone e-mail*

**STUDY PERSONNEL**: *Please list all people who will be present for the portion of the study in the MRI area, including the people who will operate the scanner, MD, nurse, etc. Please list individuals' role in this study.*
*Names Title Department Role Phone e-mail*

**BRIEF PROJECT DESCRIPTION (Please attach separate sheets if needed. Include the following information)**

*Specific Aims*

*Background and Significance*

*Preliminary Results or literature review related to this project (please attach the articles).*

*Research Plan (in detail)*

**IACUC REQUIREMENT**

*It is the investigator's responsibility to get an IACUC protocol approved by the UMass IACUC committee for all your animal studies. The PI must submit a copy of an approved IACUC protocol with the signed certification page to the Advanced MRI Center before performing any animal imaging study. The IACUC protocol must include the MRI procedures using the 3T MRI scanner.*

*IACUC docket #:*

*Title:*

*Approval Date:* *Expiration Date*:

**STUDY PLAN**

1. *What is the anticipated duration of your study?*
2. *What is your planned starting date?*
3. *How many animals do you plan to image per week?*
4. *How much time is required for each exam?*
5. *What is your preferred imaging times, if any?*
6. *Which organ do you plan to image?*
7. *What kind of disease do you plan to study?*
8. *Does the study require contrast agents? If yes, please specify them here.*
9. *Do you require special pulse sequences? If yes, please describe them here.*

10. *Do you require a special RF coil? If yes, please describe it here.*

**FINANCIAL SUPPORT**

*Scheduling priority will be given to funded studies*.

***Speedtype #:***

☐INDUSTRY SPONSOR:

*Company name:* *PI Name*

*Starting date:* *Ending date*:

☐DEPARTMENT FUNDS:

*Department Name*: *PI Name:*

*Starting date* : *Ending date*:

☐NIH Funding

*PI Name*: *Funding Type*: *Grant #*:

*Starting date:* *Ending date*:

☐OTHER

(*Please specify):*

*Starting date:* *Ending date:*

☐NONE

**PLAN FOR APPLYING FOR FUNDING**

*Funding Agents:*

*PI Name:*

*Submission Date:*

*Do you need help on the MRI part of your grant proposal? If yes, please specify*.

**PI Name** **PI Signature** **Date**

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Please email the completed application to:

Shaokuan Zheng, Ph.D.

MRI Physicist

Department of Radiology

Phone: 508-856-5122

Fax: 508-856-6250

Email: shaokuan.zheng@umassmed.edu

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# Human MRI Research Application Form

**PROJECT TITLE:**

**PRINCIPAL INVESTIGATOR**:
*Names Title Department Phone e-mail*

**STUDY CONTACTS**: (Principal Research Fellows, Study Coordinators, etc.)
*Names Title Department Phone e-mail*

**STUDY SCHEDULER:**
*Names Title Department Phone e-mail*

**STUDY PERSONNEL**: *Please list all people who will be present for the portion of the study in the MRI area, including the people who will operate the scanner, MD, nurse, etc. Please list individuals' role in this study.*

*Names Title Department Role Phone e-mail*

**BRIEF PROJECT DESCRIPTION (Please attach separate sheets if needed. Include the following information)**

*Specific Aims*

*Background and Significance*

*Preliminary Results or literature review related to this project (please attach the articles).*

*Research Plan (in detail)*

**IRB REQUIREMENT**

*It is the investigator's responsibility to get an IRB approved by the UMass IRB committee for all your studies. The PI must submit a copy of an approved IRB with the signed certification page to the Advanced MRI Center before performing the imaging study. The IRB must include the MRI procedures using the 3T scanner.*

*IRB #:*

*Title:*

*Approval Date:* *Expiration Date*:

**STUDY PLAN**

11. *What is the anticipated duration of your study?*
12. *What is your planned starting date?*
13. *How many subjects do you plan to image per week?*
14. *How much time is required for each exam?*
15. *What is your preferred imaging times, if any?*
16. *Which organ do you plan to image?*
17. *What kind of disease do you plan to study?*
18. *Does the study require contrast agents? If yes, please specify them here.*
19. *Do you require special pulse sequences? If yes, please describe them here.*

20. *Do you require a special RF coil? If yes, please describe it here.*

**FINANCIAL SUPPORT**

*Scheduling priority will be given to funded studies.*

***Speedtype #:***

☐INDUSTRY SPONSOR:

*Company name:* *PI Name*

*Starting date:* *Ending date*:

☐DEPARTMENT FUNDS:

*Department Name*: *PI Name:*

*Starting date* : *Ending date*:

☐NIH Funding

*PI Name*: *Funding Type*: *Grant #*:

*Starting date:* *Ending date*:

☐OTHER

(*Please specify):*

*Starting date:* *Ending date:*

☐NONE

**PLAN FOR APPLYING FOR FUNDING**

*Funding Agents:*

*PI Name:*

*Submission Date:*

*Do you need help on the MRI part of your grant proposal? If yes, please specify.*

**PI Name** **PI Signature** **Date**

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Please email the completed application to:

Shaokuan Zheng, Ph.D.

MRI Physicist

Department of Radiology

Phone: 508-856-5122

Fax: 508-856-6250

Email: shaokuan.zheng@umassmed.edu

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# APPENDIX B: Safety-Screening Requirements for Human Subjects

To maintain safety for subjects using our 3T Philips MRI scanner, please adhere to the following policies prior to scanning sessions.

1. To save time, please explain the screening form to the subject and ask the subject to fill out the form. Please fill out and make a copy of his or her signed consent form before coming to the MRI suite.
2. Screening for metal should be done in advance, before subjects come to the scanner.
3. If a subject does have metal in his or her body, or there is any other safety issue in need of resolution, please talk to a radiologist concerning the safety of the subject being scanned. In order for a scan to be performed on a subject with metal in his or her body, or on a subject with any other safety issue, written permission from the radiologist would have to be provided **before** the subject comes to the MR suite. We can accept reports from other hospitals verifying a subject is safe for scanning.
4. If the subject is approved for scanning by a radiologist, but there are any special health circumstances identified by the radiologist, a trained health care provider must be present during the scanning.
5. Confirm with the subject by telephone the day before the MRI scan, and remind the subject to come 15 minutes prior to the scheduled MRI time. The subject must be in hospital scrubs with all metal removed (jewelry, bras, etc) prior to the MRI scan.

# APPENDIX C: Radiologists Reading Scans

**Background:**

It is generally accepted that 1-2% of research MRI studies will yield medically significant findings (e.g., neuroimaging demonstrating presence of a CNS tumor or brain aneurysm)[1]. The question of who should interpret these data, and what action to take upon discovery of a significant incidental finding is controversial and the subject of important philosophical and ethical debate. In the absence of obvious moral and legal guidelines, the AMRIC in collaboration with the Department of Radiology has established the policy that all research studies performed on Participants are read by radiologists.

Please adhere to the following policies regarding radiologists reading scans.

1. PIs need to identify the radiologist who will read their scans ahead of time.
2. It is the MR physicist's responsibility to push data from scans on human subjects to the UMass Picture Archiving and Communication Systems (PACS). T**he studies pushed to PACS will be read by a designated radiologists collaborating with AMRIC. Since research studies are not designed for clinical diagnosis, ONLY studies with abnormal findings will be reported to the PI. Exceptions to this policy require written justification that will be considered by the AMRIC Oversight Committee.**
3. **Policy Regarding Incidental Findings: If *any* incidental findings are found in the radiologist's report, it is the PI's responsibility to notify the subject.** We have based this policy on recommendations in the literature. E.g., Wolf et al. (2008) recommend that whenever incidental findings "are to be disclosed, they should be disclosed directly to the research participant."[1] Whereas the projected net benefit to the subject of receiving notification of incidental findings varies from high to low[2,3], to maximize safety, simplicity, and the "obligations of beneficence", we require that *any* incidental findings discovered be reported to research subjects[4,5,6].
4. **Required Statement for PI's IRB:** A description of the policy that radiologist will read subject's scans, and that subjects will be informed of incidental findings, must be in the informed consent section of every PI's IRB document. Suggested phraseology follows:
    a. The MRI scan being done is designed to answer research questions, not examine you medically. This MRI scan is not a substitute for a scan a physician would order, and it may not show problems that would be picked up by a medical MRI scan. However, all MRI scans taken will be read by a clinical radiologist trained in reading MR images for safety purposes. If the radiologist thinks that there may be an abnormality in your MRI scan, the Principal Investigator of this study will contact you and help you get medical follow up tests. Note that it is possible that you could be unnecessarily worried if a problem were suspected, but not actually found. If you have a primary care physician, we can contact your physician, with your permission, and help your physician get the right follow up for you. If the study detects an abnormality in your MRI scan, then this information may become part of the UMass Memorial hospital records.

**References:**

1. Mamourian A. Incidental findings on research functional MR images: Should we look? AJNR Am J Neuroradiol. 2004. 25:520-522.
2. Wolf SM, et al., Managing incidental findings in human subjects research: Analysis and recommendations. J Law Med Ethics. 2008. 36:219-48.

3. Lo B. Responding to incidental findings on research imaging studies: now what? Arch Intern Med. 2010. 170:1522-4.
4. Miller FG, et al. Incidental findings in human subjects research: what do investigators owe research participants? J Law Med Ethics. 2008. 36:271-9.
5. Illes J, et al. Incidental Findings in Brain Imaging Research. Science. 2006. 311:783–84.
6. Orme NM, et al. Incidental findings in imaging research: evaluating incidence, benefit, and burden. Arch Intern Med. 2010. 170:1525-32.

# APPENDIX D: Code Policy

Please Note: This information was provided by Dr. Lawrence Rosenthal, and is the present policy for UMass Memorial, because UMass Memorial does not have an MR-compatible crash cart.

When a code is called, the following procedures must be followed:

- The MR Physicist must call in the code by dialing 12345, and report the emergency to the first response team.
- The research team retrieves the AED device immediately adjacent to the UMMS elevator bank at entrance to AMRIC.
- **It is imperative that no one can enter the MR scanner room with any metal objects including the AED device.** The scanner operator's primary responsibility is to monitor the entrance to the MR scanner room to ensure that no one enters who could potentially be carrying metal objects.
- The patient must be moved out of the MRI scanner room and into the patient area using MR compatible backboard or wheelchair. BCLS certified scanner operator will administer basic cardiac life support once Zones 3 and 4 are clear.
- There is wall suction and $0_2$ set up on the back wall of the hallway in case of an emergency.
- For contrast reactions: a physician is always present and will administer treatment until the code team arrives. This physician has access to a code cart kept at AMRIC and maintained by the Department of Medicine, Division of Cardiology.

# APPENDIX E: Policies for PI-Directed Scanning Experiments

For those who have had proper training, and were approved by the AMRIC to run their own experiment, please adhere to the following requirements:

(a) Both the PI and his or her group must follow all UMASS policies about working with humans and animals.
(b) To protect the health of subjects, and to comply with the policies of IRBs, all equipment for human and animal experiments are to be strictly separated. All the equipment along the wall opposite the door is for human experiments, and all the equipment along the wall next to the door is for animal experiments.
(c) No parts of an animal's body are allowed to touch the scanner directly during an experiment.
(d) Preapproval from the Advanced MRI Center is required for the use of any coil.
(e) You are only allowed to set up experiments, run experiments, and back up data from experiments on this scanner—any other activities on the scanner are strictly prohibited.
(f) At any time, the person who opens the door to the MRI console area and scanner room must sign his or her name on the entrance log-in sheet. This person must take responsibility to ensure the safety of all people or animals involved, and to ensure the proper and safe use of the scanner and all other equipment.
(g) The PI or his or her group members must fill out the equipment section of the log-in sheet if any device will be used during the period the console area and/or the scanner room are occupied. Any problems with equipment must be recorded and reported.
(h) To maintain safe laboratory practice, at least two MRI Safety Trained Individuals, besides the Participant being scanned, must be in the immediate area at all times during human experiment. That is, the Operator of the scanner and another Individual who has completed MRI safety training. When a Participant is scanned, at least one Individual must have current cardiopulmonary resuscitation (CPR) training as evidenced by a signed document and be present. For animal and phantom studies two MRI safety trained Individuals should be on site. At least one UMMS employee, student or faculty member must be present for all MRI scanning. This applies to all scanning hours including the evenings and weekends.
(i) Prior to leaving the scanner area, the PI and his or her group must make sure that all areas, equipment, and materials are clean, neat, and orderly. If you make any changes in system settings during your experiment, you must restart the system after using the scanner.
(j) The door must be closed and locked after you leave the console area.

**Please inform AMRIC Physicist at least 24 hours prior to your scheduled experiment if you need to cancel. If not cancelled 24 hours prior to your reserved time, a fee equal to 100% of the scheduled will be charged.**

**UMASS Advanced MRI Center**

# APPENDIX F: Scheduling Form

Please fill out this form when scheduling time on the scanner. For available time slots, please check the following website: http://inside.umassmed.edu/calendar_month.aspx?id=49120

PI name:_____ Telephone number:_____

Email address:_____

Project name:_____

IRB or IACUC Docket #:_____ Expiration date:_____

If the contact name is different from the PI's name, please provide the following:

Contact name:_____ Telephone number:_____

Email address:_____

Desired date of experiment:_____ Time:_____

Please briefly describe the MRI experiment you want to perform:

_____
_____
_____
_____
_____
_____

For human-subject experiments, please provide the following:

Sex:_____ Year of birth:_____ Weight:_____(lb, kg) (not to exceed 300 lbs[or 136 kg]) Patient ID Number: _____

Contrast: Yes /No If yes, please provide Agent and Dose:

_____

For animal experiments, please provide the following:

Animal type:_____ Number of animals:_____

Contrast: Yes /No If yes, please provide Agent and Dose:

_____

For phantom experiments, please provide the following:

Phantom type:_____

# APPENDIX G: Guidelines for Discounted Scanner Time

To encourage extramural funding applications that include MR imaging in UMMS research, applications for reduced scanner fees will be considered by the Oversight Committee of the AMRIC. AMRIC is subsidized by the UMMS Department of Radiology, which has elected to utilize this resource to provide investigators with reduced scanner fees explicitly for the generation of preliminary data to support grant applications. This Appendix provides eligibility criteria for supported scanner time, information on the application process and conditions for receiving AMRIC support.

***Eligibility:***

- PI must hold a faculty appointment at the University of Massachusetts Medical School
- PI must certify that there are no available funds for MRI scanner time.
- PI's primary Department must qualify (no more than 200 hours per year of reduced scanner time will be allotted to any one department). Department level limit is reviewed by the AMRIC oversight committee and subject to available scanner time.

***Application Process:***

- The appropriate AMRIC application form (Appendix A) must be completed.
- In addition to the application form, a plan for submission of MRI preliminary data for application of extramural funding must be included. Included should be grant agency, grant type, and anticipated submission date. Also included should be a description of the role of MRI in the project that is the subject of the application.
- A budget should be included detailing the amount of reduced scanner time required for the generation of sufficient preliminary data for grant submission.
- Application must be submitted to Matthew Gounis (matthew.gounis@umassmed.edu) and will be reviewed by the AMRIC Oversight Committee. The committee convenes quarterly.

***Conditions of Award***

If the application is awarded, the PI must agree to all conditions listed below:

- PI will be responsible for the following reduced fees associated with scanner use:
    - Human Research: $225/hr
    - Large Animal: $75/hr
    - Small Animal/Phantom: $50/hr
- PI and PI's team will strictly comply with all AMRIC policies and their approved IRB or IACUC protocol(s).

- The PI will provide a report that details grant applications (funding agency, application number and submission date) that include MRI data within 90 days of completion of the project.
- Any publications or presentations that are the result of the images or analysis resulting from the acquired images must include the following acknowledgement: “The project described was supported by an award from the Department of Radiology, University of Massachusetts Medical School. MRI studies were conducted at the Advanced MR Imaging Center, UMASS, with support from Shaokuan Zheng, PhD. The content is solely the responsibility of the authors and does not necessarily represent the official views of the UMASS Department of Radiology or Advanced MR Imaging Center.”