

**Policies and Procedures for New Research Proposals:  
Magnetic Resonance Imaging (MRI) Research Group  
3.0 Tesla MRI System**

Initiating new research projects using the 3.0 Tesla MRI System requires reading the policies stated in this document. The policies include procedures for submitting a new research proposal as well as scheduling scanner time on the MRI system.

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## **I. Introduction**

The University of Hawaii's Magnetic Resonance Imaging Research Group at the Queens Medical Center houses a Siemens 3.0 Tesla MRI system. This powerful imaging system can be used for both structural and functional scans of the brain and other organs.

Magnetic Resonance Imaging (MRI) system is a widely used technology in modern clinical diagnosis. It employs both a strong static and a time-varying 'switched' magnetic field as well as a rapidly oscillating radio frequency field (RF) to obtain tissue images in selected planes by virtue of the variable magnetic orientation and spin properties of the nuclei of different molecules. Various components of the MRI system enable measurements to the way molecules respond to the magnetic forces which are translated to produce images.

There are three basic components to an MRI system. There is a large, static magnetic field (e.g., 3 Tesla for the human imagers at the MRI Center), and radio frequency (RF) coils that are used as both a transmitter to excite the MR signal and a receiver to detect the MR signal. The third component, gradient coils, functions like a switch to produce linear gradients of the magnetic field for imaging.

The strength of a magnet is measured in Tesla. A 1.5 Tesla magnet is about 30,000 times stronger than the Earth's magnetic field. 1.5 Tesla scanners are typically used in clinical practice. Compared to 1.5 Tesla scanners that have been around for many years, 3.0 Tesla scanners are newer and, currently, only laboratories in major medical centers or research institutions use them. Its field strength is double that of 1.5 Tesla scanners leading to better images with higher resolution or more detail information.

The scanner uses a closed cycle refrigeration system to operate the magnet. The evaporated liquid helium that is used to cool the magnet is compressed and pumped back making the system more efficient.

Several advanced MR techniques are available for research applications, such as functional MRI (fMRI), MR spectroscopy and perfusion MRI. fMRI measures changes in blood flow and in blood oxygenation of the brain. When a particular area of a brain is activated, blood rushes in and the local blood gets more oxygen. With fMRI, we can map out brain patterns of activation by looking at changes in blood oxygenation. MR spectroscopy allows measurements of selected chemicals in selected body parts (e.g. certain brain regions). These chemicals may reflect the integrity or density of certain cell types. Perfusion MRI provides measurements of blood flow and blood volume in certain organs or tissue.

In addition to these advanced MR applications, quantitative analyses using advanced image processing tools (e.g. statistical parametric maps or SPM, FreeSurfer, etc.) are available for studies in the brain (e.g. voxel based morphometry, quantitative analyses of the BOLD signals).

## **II. Guidelines for Safety**

The 3.0 T MRI system is operated in strict adherence to existing guidelines from the Food and Drug Administration (FDA) for magnetic resonance diagnostic devices. There are potential health hazards related to the MR scanner usage such as for those with implanted devices. However, there is no evidence supporting any significant long-term harmful physiological affects to humans. The section below provides some of the safety concerns associated with MR research as well as practical implications of these safety issues.

### **1. Potential Health Hazards**

Some potential health hazards will be discussed as they relate to (1) Static Magnetic Field Strength (2) Radio Frequency (RF) and (3) Acoustic Noise.

#### **Static Magnetic Field Strength**

The static magnetic field is the main force that is ALWAYS present once the magnet is turned up to the designated field strength. Ferromagnetic metal objects have the potential of becoming projectiles when placed into the magnetic field. Serious injury may occur with objects brought into the magnetic field turn into projectiles. For example, small objects such as paper clips and hairpins can be dislodged as a person moves closer to the magnet.

The static magnetic field can also cause any ferromagnetic objects or devices, including those within the human body to become attracted and attempt to align parallel with the main magnetic field. This includes metal fragments within the eyes, aneurysm clips and other implanted medical devices. In addition, metal in or near the body can produce artifacts on the images produced.

Any magnetic fields above 4T theoretically have some effects on peripheral nerve stimulation and cardiac stimulation due to its high magnetic strength. Therefore, international guidelines require that magnetic fields be kept at or below the peripheral nerve excitation threshold and well below cardiac stimulation threshold.

Magnetohydrodynamics relates to phenomena arising from the motion of electrically conducting fluids in the presence of electric and magnetic fields. This phenomena's possible effect on human body include dizziness, nausea, and phosphenes (visual sensations arising from mechanical or electrical stimulation of the eye) and the effects become more apparent as the strength of the static magnetic field increases. Slow movement of the head within the magnetic field can minimize these effects. It is recommended that the subjects move slowly when being placed in and out of the scanner.

#### **Radio Frequency (RF)**

Radio frequency (RF) is used to create the MR signals by transmitting its energy from the transmit RF coil to the subject. There is possibility the RF field can increase local tissue

temperature as well as body core temperature. In extreme cases, this can cause tissue burning. The degree of the burning depends on the strength of the magnetic field, the repetition time, the type of RF coil used, and the subject's thermoregulation system.

This potential health hazard of electrical burns can be avoided by excluding subjects with metal devices or wires implants and prevent the wires such as ECG, EEG, and EMG from forming closed loops and are contained in proper insulating material without touching the bare skin of the subject. It is also important to place an insulating material between the subject's skin and transmit RF coil.

### **Acoustic Noise**

MR Scans produce acoustic noise as current is passed through the gradient coils during image acquisition. A loud 'knocking' noise, mostly of low frequency, can be heard when time there is change of gradients. Commonly associated problems with acoustic noise are simple annoyance, increased anxiety, verbal communication difficulties between MR operator and subject, and possible permanent or temporary hearing loss. These safety hazards for research subjects can be alleviated by wearing hearing protection in the form of earplugs or headphones during scanning.

## **2. Exclusion Criteria**

There is apparent risk if the patient has any history of injury involving metal fragments, or has some type of implanted electrical device (such as a cardiac pacemaker, joint prostheses, surgical /vascular clips, hearing aids). The ferromagnetism induced in these metal objects may cause movement of the implant that can result in injury to nearby vital structures especially in the eye or brain or bleeding resulting from the torque on aneurysm clips. Electromagnetic disturbance of a cardio pacemaker's electronic program may lead to heart dysrhythmias.

Other exclusion criteria include severe heart disease (including susceptibility to arrhythmias), wearing metal braces on the teeth, pregnancy, and/or having an intrauterine device. It is necessary to perform screenings for patients to find out if they will be "MR compatible". These screens have to be performed for each subject, using the approved MR screening form at the MR facility.

## **3. Before Entering the MR Scanner Room**

For anyone entering the MRI scanner room, it is necessary to make sure metallic objects such as the following items have been removed from clothing, pockets, body, etc.

- Earrings, bracelets, necklaces or other fashion or body jewelry
- Eye glasses (wear contact lenses if necessary)
- Removable orthodontic work
- Bras, girdles or other undergarments with wires or metal clasps
- Shoes with steel toes

- Eye shadow (these products usually have a metallic base)

Belts, beepers, hair clips, wallets, watches, keys and other common wear will be removed before entering the magnet room. A secured locker will be available. Comfortable clothing is advised for patients being scanned. As the magnet room is kept at cooler temperatures, blankets will be available if necessary.

#### **4. MR Safety Training**

A brief Safety Training Program for the PI and all research staff present during the scans will be necessary to address the potential hazards of MRI environment. Basic safety precautions will be presented in a video format and an MR Environment Screening form will be required for researchers entering the magnet room.

Components of the MR Safety Training Module:

- Safety Video from Siemens
- MR Environment Screening for “non-patient” individual
- Reading of this MR Scanner User Policy in its entirety

Investigators or assistants may not enter the scanner room without completing MR safety training. Investigators and their research personnel are responsible for preparing their study subjects for scanning, unless other arrangements are made with the MR Facility Personnel. Subjects must sign the appropriate consent and screening forms before they enter the scanner room. If there are any questions regarding a subject’s compatibility with the magnetic field, please notify one of the MRI research staff.

### **III. Operational Hours and Location**

The regular operational hours dedicated for research time and associated technical developments are weekdays, Monday through Friday, from 10am to 6pm. The scanner may also be used during off hours (after 6PM and weekends) if necessary and available.

The 3T MRI facility is located on the 1<sup>st</sup> Floor (General Service Building) of the Queen’s Medical Center (QMC).

### **IV. Proposal for Research Studies Using MRI Scanner**

Gaining access for research protocols on the 3.0 Tesla imaging system requires the completion of the following procedures:

1. Obtain UH, QMC, or appropriate IRB protocol approval(s)
2. Submit and gain approval from the MR Core Advisory Committee (discussed in detail below)
3. Schedule time on the MRI scanner (see scheduling policy)

## 1. Fee schedule

3-T MRI facility user fees are based per hour and on eligibility:

- Fully funded studies, UH-CRC supported: \$480/hour
- Fully funded studies, non-UH-CRC supported: \$600/hour
- Pilot studies, UH-CRC supported: \$240/hour
- Pilot studies, non-UH-CRC supported: \$300/hour

Note: Certified scanner operator(s) from MRI Research Group may be hired at an additional cost of \$50 per hour if requested.

## 2. MR Core Advisory Committee

The MR Core Advisory Committee can provide support with protocol planning, theoretical and practical aspects of the research. Technical aspects of MRI project from data acquisition to analysis methods can be discussed with the directors of the committee.

### MR Core Advisory Committee

Linda Chang, M.D.	MR Core Director	Neurology / Neuroscience	<a href="mailto:lchang@hawaii.edu">lchang@hawaii.edu</a>
Thomas Ernst, Ph.D.	MR Co-Director	MR physics / Neuroscience	<a href="mailto:tmernst@hawaii.edu">tmernst@hawaii.edu</a>
David Easa, M.D.	Member	Neonatology	<a href="mailto:easad@hawaii.edu">easad@hawaii.edu</a>
William Haning, M.D.	Member	Psychiatry / Addiction	<a href="mailto:haning@hawaii.edu">haning@hawaii.edu</a>
Andrew Stenger, Ph.D.	Member	MR physics / Neuroscience	<a href="mailto:stenger@hawaii.edu">stenger@hawaii.edu</a>
Irwin Schatz, M.D	Member	Cardiology / Internal Medicine	<a href="mailto:schatzi@hawaii.edu">schatzi@hawaii.edu</a>
QMC representative (TBD)	Member	Queen's Medical Center	

\* Dan Alicata, M.D., Ph.D. (alternate member) – Adolescent Psychiatry  
(dalicata@pol.com)

The MR Core Advisory Committee is responsible for review and approval of all study protocols. Complete proposals will be reviewed by the MR Core Advisory Committee on a quarterly basis.

The review process will determine if the proposed research is appropriate with the technology available and whether the investigative team is prepared to carry out and analyze the experiment. The MR Core Advisory Committee will also identify any potential problems arising from the studies (software, hardware, data processing issues) during the proposal review.

Approval of the proposal does not guarantee the investigator time on the scanner. The investigator will need to schedule scanner time with the Scanner Coordinator after the study is approved.

Before submission of your study, research proposal outlines may be discussed with MR Directors, Linda Chang, M.D. and Thomas Ernst, Ph.D. Please keep in mind that the MR Core Advisory Committee will give priority to NIH-funded projects or new investigator-initiated protocols. Support may be provided for pilot studies utilizing MRI techniques and have potential to develop into full NIH proposals, especially those related to drug abuse, HIV, or aging or brain development studies.

If an investigator requests scan time to gather preliminary data for a pilot study in support of a grant proposal, free pilot hours may be granted. However, justifications must be provided to explain why departmental funds or other pilot funds are unavailable.

### **3. Submission of proposal to IRB and the MR Core Advisory Committee**

It is advised research protocols be first submitted to the appropriate IRB, and approval obtained, before submission to the MRI Core Advisory Committee. The protocol and the proposal may be submitted concurrently but the research is not to be conducted without approval of both the MR Core Advisory Committee and the IRB. After both approvals are obtained, a project number will be assigned and user time on the scanner can be scheduled with the program's research coordinators (see scheduling policy below).

The following information is required to complete the proposal:

- Principal and co-investigator(s), if any
- Date of proposal
- Faculty sponsor (if any)
- Project title
- Department and Institution of PI
- Phone number and e-mail address of PI
- Billing/account address where invoice will be sent
- Existing funding source(s) of the project
- Total number of scanner hours requested for project duration
- Total estimated duration of the project
- Data analysis methods (name of software and type of analysis)
- Additional required equipment (such as response box, physiological monitoring equipment, etc)
- IRB information (proposal can be submitted before IRB approval is obtained but a project account will not be established until IRB approval is received)
- If requesting free pilot hours, provide reasons why departmental funds were unavailable
- **Attach protocol for research project (background information, significance, preliminary data, methods, expected results, etc.) or the original grant application that includes the protocol. If the application has been submitted and reviewed, include the summary statement from the funding agency**
- **Attach Curriculum Vitae of PI**

- **Attach copies of IRB approval letters, if applicable**

Send completed proposal form and all attachments by email to [lchang@hawaii.edu](mailto:lchang@hawaii.edu) (Linda Chang, M.D., MR Core Director) or [tmernst@hawaii.edu](mailto:tmernst@hawaii.edu) (Thomas Ernst, Ph.D., MR Co-Director). Also submit a signed original proposal by mail or fax:

Linda Chang, M.D.  
UH JABSOM Dept of Medicine  
1356 Lusitana St., 7<sup>th</sup> Floor  
Honolulu, HI 96813  
Fax: 808-586-7486

## **V. Scheduling Policy**

MRI scanner time is a valuable and expensive resource and efficient use of the instrument is an utmost importance. Be aware that current and ongoing projects take precedence over newly approved projects and pilot studies.

1. All new scans will be scheduled by Laura Holmes (please contact 585-5156). Scheduling will be handled on a first-come-first-serve basis according to the time stamp on the e-mail. Scheduled scans will be confirmed via email.
2. When requesting a scan, please be clear and specific about the study details. The following items should be included on the e-mail:
  - a) PI name and contact information (phone and email)
  - b) Project Title for the study
  - c) All dates for scans requested
  - d) The preferred START and END time (hour) of the scan
  - e) Subject ID number and/or initials
  - f) Other special requests (required equipment, etc.)

For scheduling changes or cancellation (give at least 24-hours notice), please call the MRI research lab at (808) 585-5156 to be certain the requested changes have been made. It should be understood that there will be occasional difficulties with subject scheduling (tardiness or absences) or equipment problems beyond the investigator's control. Effort will be made to fairly reschedule the scan at a suitable time if necessary.

After each request of scanner time, past efficiency in use of the user's assigned scan time will be reviewed for the purpose of improving efficiency of magnet use. Frequent cancellations of the user's assigned scan time will result in billing the user for future non-use of scan time.

## **VI. Post-scanning**

Upon completion of scan, please follow the guidelines below:

1. Clean up any untidiness resulting from the patient scan. This includes returning all equipment to its appropriate storage space, placing soiled linens in the laundry hamper, etc.
2. Request a follow-up scan if applicable
3. After data have been collected, we can create a copy for your use if you will be processing the data outside the 3.0 Tesla MRI facility
4. An invoice will be generated and sent to the appropriate billing address

## **VII. Patient Confidentiality Notice**

Federal Privacy Regulations provide safeguards for privacy, security, and authorized access to health information. The confidentiality of all study-related records will be kept according to all applicable laws. The MRI Research group will not share any information and/or data gained about the subject to other investigators or any other individual unless consented by the investigators on both sides.

An assigned code composed of numbers and initials unique to our studies will be used by personnel to track patient data.