



SUBJECT: University MRI 3T Scanner Utilization	Effective Date: 04-10-2017	Policy Number: 10.8.2	
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	Responsible Authorities: Division of Research Vice President for Research		

I. BACKGROUND

FAU's Division of Research has contracted University MRI Diagnostic Imaging Centers (UMRI) to provide FAU Principal Investigators access to a General Electric Signa HDXT (TwinSpeed) 3T MRI scanner. Access to UMRI is managed by FAU to assure compliance with established policies for the protection and welfare of human subjects participating in research, manage contractual obligations, and recover charges for services.

II. PURPOSE

The purpose of this policy is to establish uniform procedures to provide access to the UMRI 3T scanner.

III. POLICY

Projects which require access to the UMRI 3T scanner shall be coordinated via the procedure described in this policy. Review, authorization, and prioritization of UMRI 3T scanner projects is determined by the FAU MRI Committee. Scheduling, compliance, invoicing, and training are managed by the Human Imaging Core (HIC) Director.

To obtain UMRI access:

1. Eligible Principal Investigators must be tenured, tenure earning, or permanent FAU faculty.
2. Proposed scanner time must be in support of an organized research project.
3. FAU compliance and FAU MRI Committee approvals must be obtained to schedule scanner use.

IV. PROCEDURE

In order to gain access to the UMRI 3T scanner, the following procedure will be used:

1. Investigators are encouraged to contact the HIC Director for an initial consultation regarding their project.
2. Eligible investigators will then submit an application to the FAU MRI Committee Chair (by email) for each project that requests use of the UMRI 3T. This application will be evaluated based upon:
 - Scientific merit and significance
 - Technical feasibility
 - Relevance to FAU's research mission
 - Project funding status

Applications should minimally include (2-3 pages maximum):

- Project title
- Investigator contact information
- Investigator department, college, and center/institute affiliation(s)
- Project manager contact information (if different)
- System requirements
- Data analysis and description
- List personnel who require data access
- Institutional Review Board (IRB) project number and approval date (if available)
- Total hours of UMRI 3T scanner time requested
- Timeline for scanner use
- Whether FAU MRI Technologist support is requested for scanning
- Summary of study, including: rationale, significance, experimental design, imaging protocol, and data analysis
- Explanation and scientific justification of proposed scanning session(s) design
- Other special requirements or considerations

Expedited review may be requested, e.g., if the study protocol requires the recruitment of rare patient types or requires pilot data to respond to a Request For Applications (RFA) with a short deadline (between announcement and submission deadline). If an expedited review is granted, the FAU MRI Committee will provide application results within 72 hours of receipt. In order to facilitate expedited review, only 50% of committee membership is required for a voting quorum.

The committee may request the applicant to provide additional information (either in person or by correspondence prior to a decision).

3. After review, the FAU MRI Committee will issue a letter of determination to the applicant via e-mail indicating either:
 - a. Approval¹
 - b. Approval with changes¹
 - c. Denial²

¹ To include: assigned priority, approved study hours, and other authorized project details

² To include justification and any recommendation(s) for future applications

4. To expedite scanner scheduling, it is recommended that investigators also apply for IRB project approval either prior to, or in concurrence with, scanner application review (as well as any other additional compliance approvals that may be required).
5. Upon approval by the FAU MRI Committee, investigators should contact the HIC Director to schedule scanner use. Additional information will need to be provided regarding safety, training, and compliance.
6. The HIC Director will schedule investigator scanner time once safety, training, and compliance criteria have been met and will assist with scanner use.
7. Project timeline will not exceed IRB approved timeframe (one year) and project deadline will be provided by the FAU MRI Committee upon project review. Renewal applications may be submitted to the committee if the project needs to continue past its approved deadline, but should include additional information about how the scanner was utilized during the previous approval phase as well as any changes to the experiment or procedure (along with the original project application).
8. A fixed hourly rate will be provided for the study. Billing frequency will be determined by the HIC Director based upon approved study sessions.

Appeal process

In the event that a project is denied approval by the FAU MRI Committee, an appeal may be made, within 30 days, to the FAU Office of the Vice President for Research. Appeals should include the letter indicating denial.

V. ROLES AND RESPONSIBILITIES

Oversight of access to University MRI contract services lies within the Office of the Vice President for Research. A duly organized FAU MRI Committee is responsible for the review, selection, and prioritization of access to the scanner. The HIC Director is responsible for IRB compliance verification, safety training, scheduling, and standard operating procedures.

Principal Investigator Responsibilities:

- Assuming overall responsibility for all aspects of research related to UMRI 3T scanner use.
- Ensuring the safety of participating human subjects as well as ensuring that such research does not proceed without necessary FAU, IRB, and regulatory approvals,
- Gaining familiarity with this policy, FAU MRI scanner policies and the HRPP, acquiring appropriate training and education, and accepting continuing responsibility for compliance with applicable policies through all stages of the research process.
- Ensuring that adequate funds are available for UMRI 3T scanner use.

FAU MRI Committee:

The FAU MRI Committee consists of up to 9 members, comprised of faculty or staff representatives from relevant departments, including MRI users, research program managers, and administrators. The committee chair and members are appointed by the Vice President for Research and serve without term limits. The FAU MRI Committee meets monthly, or as needed.

The FAU MRI Committee will be responsible for:

- Reviewing all projects that wish to use the UMRI 3T scanner within 30 days of submission. Based on its review, the committee may approve, require modifications, or deny applications. The committee will also establish project priority.

- Notifying applicants of review results and priority by email (letter from the committee Chair) within 30 days of application receipt. If an application is denied, the committee will provide applicant with additional explanation regarding application denial.
- Ensuring that none of its members participate in the review of a project if such participation would constitute a conflict of interest or cause the appearance of a conflict of interest. A member with an application under consideration by the committee may be present to answer questions from the other members, however they must be excused when their application is being evaluated and voted upon. In addition, members are strongly cautioned to be especially sensitive in avoiding conflict of interest situations, or the appearance of a conflict, to protect their own, their Department's and the University's reputation. This includes projects from the member's own department, if the member has more than a casual interest in the project.
- Conducting official business only when a quorum (one more than half the committee members) is present. Actions of the committee shall be determined by simple majority vote after proper motions have been made, seconded and discussed. Minutes will be recorded for all committee meetings noting official business decisions, and made available to the Office of the Vice President for Research upon request.
- Assisting HIC Director in development of policies related to the use and safety of scanner, personnel, and patients.

Office of the Vice President for Research Responsibilities:

- Overall responsibility for access to the UMRI 3T scanner.
- Overseeing the creation, implementation, and maintenance of this policy and the UMRI contract.
- Appointment of the FAU MRI Committee membership and Chair.
- Conflict resolution for use of the UMRI 3T scanner.
- Enforcement of this policy and ensuring that the HIC staff has the necessary authority to administer access to the UMRI 3T scanner and its safe use.
- Interface with UMRI to ensure contractual terms are met.
- Establishing UMRI 3T scanner use rates.

Human Imaging Core Director Responsibilities:

- Scheduling UMRI 3T scanner use and ensuring that all policy criteria have been met.
- Developing and making available UMRI 3T safety and compliance requirements and policies.
- Providing or facilitating training for FAU personnel involved with UMRI 3T scanner use.
- Developing and making available FAU MRI standard operating procedures.
- Tracking, invoicing, and billing for UMRI 3T scanner use.

POLICY APPROVAL

Initiating Authority

Signature: _____



Daniel Flynn, Vice President for Research

Date: 4/24/2017