



*Division of
Administrative Affairs*

MRI Safety Committee Policy #002

**MRI Safety Committee (MRISC) Protocol and
Amendment Review**

Version #1

Effective: 09/01/2024

Revised: New Document

1. PURPOSE:

FAU's MRISC has developed a strategic review process for MRI protocol and amendment submissions. The purpose of this policy is to provide guidance to Research Personnel regarding the administrative process for MRI protocol and amendment review once submitted to EH&S.

2. POLICY STATEMENT:

- 2.1. The Florida Atlantic University MRISC is responsible for ensuring that all use of FAU MRI is in compliance with federal and state regulations and FAU policies, and are consistent with the standard of care in the industry as outlined by the American College of Radiology.
- 2.2. All protocol and amendment applications must be submitted directly to EH&S at ehs@fau.edu.
- 2.3. All protocol and amendment applications that require committee to review, as defined in Section 5.4, must be submitted to EH&S by the application deadline for the monthly MRISC meeting. While every effort will be made to process reviews quickly, applications requiring committee review submitted after the application deadline may not be reviewed by the committee until the next scheduled monthly meeting. Refer to the MRI Safety Committee website for more information.
- 2.4. Only completed applications submitted by the application deadline will be reviewed at the monthly meeting. Any application that is missing documentation will not be eligible for review until all completed documents are received by the application deadline prior to the next scheduled monthly meeting.
- 2.5. EH&S will confirm that all personnel listed on the MRI protocol have completed any required safety training.
- 2.6. EH&S will verify relevant IBC, IACUC, RSC, and IRB approvals required for each MRI protocol before final approval will be granted and the MRI Facility notified that the research involving use of FAU MRI can commence.
- 2.7. Protocols or amendment applications using research animals require pre-review and

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approval from the FAU Veterinarian or alternate before the protocol will be reviewed by the MRISC.

2.8. Protocols or amendment applications using human subjects require pre-review and approval from the MRMD before the protocol will be reviewed by the MRISC.

2.9. Pilot studies must be described in a new protocol.

3. CONCEPTS AND DEFINITIONS:

3.1. **FAU MRI** – Any MRI equipment owned and operated by FAU.

3.2. **MRISC** – Magnetic Resonance Imaging (MRI) Safety Committee

3.3. **MRMD** - Magnetic Resonance Medical Director (MRMD), a radiologist or physician who is trained and certified in MRI safety and oversees the clinical aspects of the MRI Safety Program. The MRMD is the Chair of the MRI Safety Committee and may also be the medical director for one or more of the MRI facilities at FAU.

3.4. **PI** – A Principal Investigator, the individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project.

3.5. **Prescreening Activities** – Researchers approved by the MRMD and provided additional training by MRI Facility personnel to prescreen human subjects prior to their visit to FAU for MRI procedures. These prescreening activities will include a thorough review of the screening requirements and outlining minimum requirements for documentation that must be presented to MRI Facility personnel prior to participation in scanning activities (if applicable.)

3.6. **IACUC** – The Institutional Animal Care and Use Committee, responsible for oversight of the animal care and use program and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and the Guide for the Care and Use of Laboratory Animals. Its oversight functions include an ongoing assessment of animal care and use.

3.7. **IRB** – The Institutional Review Board (IRB) is responsible for oversight of the use of human subjects in research and to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under FAU.

3.8. **IBC** - The Institutional Biological Safety Committee (IBC) has been delegated the authority to set University policy with regard to research with recombinant/synthetic nucleic acid molecules, biological materials, and select agents and toxins. The IBC is

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responsible for reviewing projects that involve, but are not limited to, recombinant DNA, RNAi, pathogens, human materials and other potentially infectious material, as well as transgenic animals.

3.9. **RSC** – The Radiation Safety Committee (RSC) is delegated the authority to promulgate and administer policies and procedures for the FAU Radiation Safety Program with regard to radiation safety for radioactive material at FAU. The RSC reviews and approves all use of radiation at FAU including research, clinical, and academic applications.

4. RESPONSIBILITIES:

4.1. The **Principal Investigator (PI)** will be responsible for:

- Assuring that all MRI protocols and/or amendments are submitted to EH&S by the deadline dates and are renewed at appropriate intervals to avoid expiration of a protocol.
- Assuring that procedures are performed as described in the corresponding approved MRI protocol and if necessary, submitting an amendment to the protocol and awaiting approval before new method(s) will be introduced.
- Ensuring that all personnel have completed required training.
- Ensuring compliance to all applicable Federal, State and University regulations and policies pertaining to the use of FAU MRI.
- Completing all required institutional training.
- Reviewing and adhering all institutional policies as applicable to their research.

4.1. The **MRISC** will be responsible for:

- Providing oversight for all use of FAU MRI conducted.
- Reviewing and approving, requiring modifications (to secure approval) or withholding approval of MRI protocols and/or amendments.
- Assuring that all personnel conducting work with FAU-MRI are appropriately trained.
- Supporting the expertise of medical and veterinary personnel on the committee with regard to the use of human subjects and animals, respectively, in the use of FAU MRI.

4.2. The **MRI Medical Director (MRMD)** will be responsible for:

- Providing medical oversight and ensuring the safety of all FAU MRI operations.
- Consulting with FAU faculty and students regarding study design and conduct prior to and throughout the lifecycle of an MRISC protocol.
- Consulting with the FAU Veterinarian or alternate regarding study design and conduct prior to and throughout the lifecycle of an MRISC protocol involving the use of animals.
- Providing guidance to MRISC members regarding medical and

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operational requirements, as well as input on logistical and environmental issues as part of MRISC protocol review.

4.3. The **Office of Environmental Health and Safety (EH&S)** is responsible for:

- Administrative support of the MRISC members to facilitate their regulatory function.
- Maintaining policy and assure regular review and update as necessary by the MRISC.
- Confirmation that all research personnel have completed all required MRI training.

4.4. The **FAU Veterinarian or alternate will be responsible for:**

- Veterinary review of MRI protocol and amendments involving the use of animals.
- Providing veterinary care as described in all MRI approved protocols.
- Providing guidance to MRISC members regarding medical and operational requirements for research animals, as well as input on logistical and environmental issues as part of MRISC protocol review.

5. PROCEDURES:

5.1. Administrative Pre-Review

In collaboration with MRI Facility personnel, EH&S will perform a pre-review of all protocol or amendment submissions to determine if the application is complete and all applicable sections are addressed. Comments may be directed back to the Principal Investigator requesting modifications prior to submitting for MRISC review. The PI will submit the revised protocol to EH&S. EH&S will assign the revised protocol for Medical/Veterinary Pre-review and MRISC review.

5.2. Veterinary Pre-Review

The protocol or amendment that involves the use of animals will receive Veterinary pre-review from either the FAU Veterinarian or Alternate. If the Veterinarian requests for modifications, the PI will be notified by email from EH&S. The PI will submit the revised protocol and EH&S will review the protocol for completeness of response and review with the FAU Veterinarian or alternate to ensure compliance with all requirements prior to MRISC review.

5.3. Medical Pre-Review

All protocols or amendments will receive medical pre-review from either the MRMD or Designated Representative. If the MRMD or Designated Representative requests for modifications, the PI will be notified by email from EH&S. The PI will submit the revised protocol and EH&S will review the protocol for completeness of response and review with the MRMD or Designated Representative to ensure compliance with all

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requirements prior to MRISC review.

5.4. Committee Review

Committee review is required for all new protocols and all protocols referred to committee review by the MRI Medical Director or any member of the MRISC, and all amendments with significant changes (as outlined below.) Committee review will only occur at a convened meeting of a quorum of the MRISC members and with a formal vote. A lead reviewer is assigned to facilitate the review of the protocol or amendment at the meeting. Following the presentation of the protocol or amendment by the lead reviewer, discussion is held and a motion is made from the members to approve, require modifications to secure approval, require modifications and additional committee review, table or withhold approval. All motions must be seconded and approved by the majority of the members to pass.

If the committee votes to request modifications to secure approval, the PI will be notified by email from EH&S. The PI will submit the revised protocol or amendment and in collaboration with the MRI Facility personnel, EH&S will review for completeness of response prior to further committee review.

If the committee votes to request for additional review following the committee review, the protocol or amendment will be assigned to at least one MRISC member for review. A list of required modifications will be sent to the PI and the PI will be required to submit the revised application to EH&S. The application will then be routed for additional review as described below.

If the committee votes to table, the protocol or amendment will be reviewed at the next convened MRISC meeting. A list of required modifications will be sent to the PI and the PI will be required to submit the revised application to EH&S and reviewed at the next scheduled meeting.

If the committee votes to withhold approval a written notification will be sent to the PI indicating the reasons justifying such an action. The PI is invited to meet with the MRISC committee and address the MRISC's concerns in writing.

5.5. Amendments

Amendments can be any significant or minor change requested to an approved MRI protocol. Significant changes are reviewed and approved through committee review and minor changes are reviewed and approved through Administrative Review. Significant changes will most likely require corresponding modifications to current IACUC and/or IRB protocols as applicable.

5.5.1. Significant Changes

- Change to imaging protocol
- Change in imaging objectives
- Change in Principal Investigator

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- Change that impacts personnel safety
- Addition of research personnel who will require access to Zone IV during scans
- Addition of research personnel who will conduct prescreening activities
- Changes in study which impact capabilities/capacity of the MRI Facility

5.5.2. Minor Changes

- Correction of typographical errors
- Correction of grammar
- Change in contact information
- Change in personnel; other than those listed under “significant changes”. All personnel must complete required trainings.

5.6. Administrative Review

The minor changes listed in 5.5.2 do not require committee review and may be reviewed and approved administratively by EH&S in coordination with MRI Facility personnel.

6. RELATED INFORMATION:

- MRISC Policy 001 – MRI Safety Committee Role and Function
- MAN15 – MRI Safety Manual

Approved and issued by order of:



Stacy Volnick, PhD
Interim President, FAU
Vice President Administrative Affairs

8/21/2024
DATE:

POLICY MAINTENANCE SECTION

Last Revision Date	New Document
Last Revision By	Wendy Ash Graves
Next Review Due	09/01/2027
Review Frequency	3 years

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Version	1
Time-sensitive Items	N/A

THIS POLICY RESCINDS ALL OTHER WRITTEN DIRECTIVES REGARDING THIS TOPIC.

7. RECORD OF CHANGES/STATUS CONTROL:

Version	Date	Summary of Changes	Reviewed By
1	09/01/24	New Document	<ul style="list-style-type: none">• W. Ash Graves• A. Newberg• MRISC