

UNIVERSITY
OF MIAMI
DEPARTMENT of PSYCHOLOGY



RULES AND REGULATIONS

**University of Miami Department of Psychology MRI
Facility**

I. MISSION

The University of Miami Neuroimaging Facility in the Department of Psychology was created in order to permit and promote interdisciplinary neuroscience research. In accordance with the goals of the University of Miami, the mission of the facility is to acquire, advance and disseminate knowledge of neuroscience and psychology. The facility is dedicated to informing research through the use of structural and functional magnetic resonance (fMRI) techniques, to improving imaging technology, and to educating the academic and public communities.

II. ADMINISTRATIVE STRUCTURE AND STAFF

The administrative team encompasses several individuals and committees. All committee members are University of Miami faculty and staff.

Director: Pradip Pattany

Assistant Director: Ekaterina Denkova

Responsibilities:

- Provides leadership in administration and technical direction.
- Coordinates and directs operational activities of the MRI Facility.
- Leads MRI Management Committee.
- Ensures the various MRI subcommittees meet regularly and executes duties assigned.
- Participates in each MRI subcommittee.
- Supports the neuroimaging faculty and research teams using the MRI Facility.

Management Committee:

Chair: Pradip Pattany

Members: Phil McCabe, Jennifer Britton, Aaron Heller, Amishi Jha, Elizabeth Losin, Roger McIntosh, Ekaterina Denkova, Elizabeth Reyes, Andre Perwin, Melyza Casanova, Derek Harmison

Responsibilities:

- Provides administration, technical direction, and long-range planning for the facility.
- Design and implement procedures and policies with committees.
- Set and monitor policy, including guidelines for day-to-day operations.
- Approve University of Miami and non-UM faculty member's use of the MRI facility to conduct their research.
- Promote the facility and the science conducted.
- Sponsor regularly scheduled seminars to the academic and public community.

MRI Review Committee

Chair: Pradip Pattany

Members: Roger McIntosh, Aaron Heller, Ekaterina Denkova

Responsibilities:

Evaluate the quality and feasibility of proposed studies.

Provide constructive feedback regarding the study design.

Allocate scanner time.

Safety Committee

Chair: Pradip Pattany

Members: Elizabet Reyes, Jennifer Britton

Responsibilities:

Achieve maximum safety for users, subjects, and staff.

Oversee and manage safety training sessions.

Approve peripheral equipment used in the scan room.

Technical Committee

Co-Chair: Aaron Heller and Roger McIntosh

Members: Pradip Pattany, Derek Harmison, Jennifer Britton, Elizabeth Losin

Responsibilities:

Recommend purchases of peripheral equipment.

Provide equipment trainings to users.

Monitor peripheral equipment-related issues.

Create data processing stream.

Monitor server issues.

Provide technical assistance regarding general equipment issues.

Antonio Orlando Award Committee

Co-Chair: Aaron Heller and Roger McIntosh

Members: Ekaterina Denkova

Responsibilities:

Prepare and post announcement on annual basis.

Review applications and select awardees.

Coordinate post-award presentations.

The committees will meet, when necessary, as determined by the Chair. Committee decisions will be reached as much as possible by consensus. When no consensus can be reached, the decision will be made by simple majority.

Part-time Physicist (Pradip Pattany)

Responsibilities:

Maintain scanner functioning and image quality.

Develop and oversee Quality Assurance procedures.

Develop MR sequences for utility across laboratories.

Assist the investigators with the technical details necessary to perform their studies.

Maintain relationship with GE maintenance.

Upgrade system when determined necessary.

Communicate any system upgrade or changes to the community of investigators.

Supervise the MRI technologists.

MRI Technologists (Elizabet Reyes)

Responsibilities:

Maintain utmost safety for research participants and staff.

Provide safety training for all users.

Execute Quality Assurance procedures.

Notify investigators of any scan issues.

Review metal screen and pregnancy release form prior to scanning.
Communicate any scheduling issues.
Communicate with research team regarding group's needs.
Maintain order during scanning sessions.
Help position the subject.
Operate the MR scanner.
Maintain appropriate logs (i.e., safety training, MRI sessions, Q+A, etc).
Download data to the server and DVD for facility and investigator.
Communicate supply needs to the Administrative Assistant.
Schedule and supervise cleaning of MRI facility (Zone IV).

Administrative Assistant (Melyza Casanova)

Responsibilities:

Support the activities of the Director.
Field and respond to inquiries regarding facility use.
Monitor and approve MR study scheduling.
Obtain payment for scans.
Order equipment.
Maintain supplies necessary for scanning.

Information Technology (Andre Perwin, Derek Harmison)

Responsibilities:

Maintain server space for data storage (facility copy).
Maintain departmental equipment.
Assist individual investigators maintain space on departmental servers.
Solve or recommend solutions to technological challenges involving access and space.

Principal Investigators (Jennifer Britton, Aaron Heller, Elizabeth Losin, Roger McIntosh, Amishi Jha, Ekaterina Denkova)

Responsibilities:

Provide description and needs of each experimental protocol, in advance of first scan.

Provide emergency contact list to the facility.

Obtain and maintain safety training for all members of the research group.

Instruct research group of procedures regarding facility, equipment and study-specific protocols.

Communicate any safety concerns or equipment issues to the MRI community.

Provide adequate and trained personnel during scans.

III. FACILITIES AND EQUIPMENT

Facilities

The 1200 square foot MRI facility is housed on the first floor of the three-floor, 37,700 square foot Neuroscience building located at 5151 San Amaro Drive, adjacent to the Cox Science Building on the University of Miami Coral Gables Campus. The facility encompasses a MR scanner suite (Rooms 104A-H) with associated reception and waiting areas, dressing rooms, a MR simulator/mock scanner suite (Room 102) and four behavioral testing rooms (Room 124A, 124B, 126A, and 126B). The behavioral testing rooms range in size from 45 to 81 square feet and come equipped with a table, chairs, and a phone to comfortably conduct data collection.

The MRI suite houses a 3T MRI scanner; therefore, the ground floor has several zones that correspond to the safety levels associated with the 3T magnet. Entrance to the different zones is controlled to maintain a secure environment for research participants and staff.

Zone I is freely accessible by individuals working in the building. No special screening is required to be in Zone I.

Zone II is designated for pre-screening. Zone II includes two separate areas. One area is intended for simulation of the scanning procedures via mock scanner (Room 104C). The second area is intended for research participants reporting for research scans and consists of a waiting area, dressing room and restroom. Zone II is accessed from the reception/waiting area and is controlled by card reader access. Access is granted to UM personnel after completing all necessary safety training. All individuals participating in a research scan must complete a metal screening form and sign a pregnancy release form, if applicable, in Zone II before undergoing an MR scan.

Zone III includes the control room (104F), a viewing room (104B) and the equipment room (104D). This zone is accessed from Zone II through card reader access. Only key personnel (MR technologist, trained research staff, and the research participant) should have access to this area. Research participants must complete the metal screen, confirm that they are not pregnant and remove all metal from their person prior to entering this zone. In the event that the research participant is a minor, a parent may accompany the child to Zone III but must complete the same procedures (metal screen, etc.). Research staff must complete a metal screen annually during safety training and notify the Facility of any changes prior to entering this area. Only the designated, certified MRI Technologist and/or designated MRI Physicist will operate the scanner, and the MRI Physicist will work with PI to implement and optimize the protocols.

Zone IV is the scan room (104E). This zone is accessed through a locked door from Zone III. Only key personnel should enter this room when accompanied by designated certified MRI Technologist and/or designated MRI Physicist, and this door should remain closed and locked unless in use. If not already, all metal must be removed from anyone entering this room. No equipment may enter this room unless it is inspected by the safety/technical committee.

No metal objects should be allowed into Zones III or IV. Lockers are provided for research participants and staff to remove any metal items (e.g., paper clips, bobby pins, USB drives,

jewelry, cell phones, credit cards, etc.). A metal wand may be used to confirm any of these items are not brought into the other areas.

If an emergency occurs that requires medical attention, individuals should be moved to this area (Zone II) so that medical equipment is not brought into Zones III and IV.

Equipment

The Imaging suite has a state-of-the-art Siemens Magnetom Vida 3.0T MRI Scanner (Erlangen, Germany). It is a wide bore whole body scanner with high performance gradient system and phased array coils to provide highest possible image quality. It can perform advance structural and functional imaging for neuro, cardiac, abdominal, and orthopedic imaging. The MR suite is equipped to deliver visual, auditory, and tactile stimuli as well as record behavioral responses. Supplementary equipment to record physiological responses and eye-tracking are also available. In addition, it has Resoundant Hardware to perform MR elastography of the Liver. Comparable equipment may be replaced at any time, if necessary.

Details of the equipment available to users are outlined below:

- Siemens Magnetom Vida 3.0T MRI Scanner (<https://www.siemens-healthineers.com/en-us/magnetic-resonance-imaging/3t-mri-scanner/magnetom-vida>)
- Hyperion MRI Digital Projection System (<http://www.pstnet.com/hardware.cfm?ID=90>)
- Resonance Technology Presentation/Eye-tracking system (http://www.mrvideo.com/product/products.asp?id=10&sub_id=14)
- MR compatible prescription glasses (<http://www.pstnet.com/hardware.cfm?ID=93>)
- Current Designs Fiber optic response system (<http://www.curdes.com/>)
<http://www.curdes.com/mainforp/responsedevices/hhsc-1x4-1.html>
<http://www.curdes.com/mainforp/responsedevices/hhsc-1x4-d.html>
<http://www.curdes.com/mainforp/responsedevices/hhsc-1x5-n4.html>
<http://www.curdes.com/mainforp/responsedevices/hhsc-trk-2.html>

- Biopac MP150 Physiological Recording System (<http://www.biopac.com/Research.asp?SubCatId=91&Main=Systems>) with the following modules:
 - Skin conductance <http://www.biopac.com/eda-gsr-amplifier-mri>
 - Heart rate <http://www.biopac.com/pulse-plethysmogram-amplifier-mri>
 - ECG <http://www.biopac.com/ecg-electrocardiogram-amplifier-mri>
 - Respiration <http://www.biopac.com/respiration-amplifier>
 - Stimulator <http://www.biopac.com/programmable-stimulator-module>
- Video Camera Monitoring (<https://mrc-systems.de/en/products/mr-compatible-cameras>)
- Gustometer (Taste-Delivery)
- Mock Scanner (custom-built by Midwest Composite) (<http://midwestcomposite.com/models.php>)
- MoTrak Head Motion Tracking System (<http://www.pstnet.com/software.cfm?ID=96>)
- Resoundant for MR Elastography (<https://www.resoundant.com/>)

NOTE: As technology evolves, the above equipment may be replaced by alternative devices. Please check with the facility's Technical Committee for current list of peripherals. Facility is not responsible for the operation of third-party peripheral equipment.

IV. REGULATIONS

The safety of visitors to the facility, whether or not subjects in a study, and of the facility staff is of paramount importance and takes precedence over any research considerations and over the convenience of any investigator. For this reason, the facility has prepared a manual of safety procedures (see the Safety Manual), which is strictly adhered to at all times. The Technical Committee ensures compliance with these procedures and updates the manual as needed and, in any case, reviews it annually. All personnel working at the facility must participate, once a year, in safety training.

The facility is prepared to study a range of research participants including: normal adults, elderly subjects, adolescents, children, and patients with stable conditions compatible with MR imaging. At present, there is no provision for the use of contrast materials or for sedation. None of the

studies to be conducted at the facility have a clinical purpose and there is no medical or radiological staff on the premises.

Research Proposals

There are two separate requests that need to be made in order to scan at the facility. The first request via letter of intent is submitted prior to grant submission. The second request via scan time request occurs after the grant is awarded and prior to scanning the first subject.

– Letter of intent

Before submitting an external grant request that involves neuroimaging, the investigators are urged to submit a letter of intent to the facility's MRI Review committee to make certain that the facility is prepared to commit the resources necessary for the particular study. The facility will not be required to honor scanning requests for funded studies unless a prior agreement was reached.

Requests are to be accompanied by a brief description of the proposed study in which the hypothesis is clearly stated along with a rationale, description of the subjects to be scanned, their number, and the specification of the protocol to be used. There also should be a brief statement regarding the type of analysis to be performed. The funding source or indication of where the investigator plans to seek funding once the pilot studies have been completed should be indicated. Proposals should be, on average, 3 to 4 (double spaced) pages in length.

All studies will be subject to a review by the MRI Review Committee. Each proposal will be reviewed by three referees from within or outside the committee as appropriate. Approval of a proposal depends on its feasibility, merit and availability of time on the magnet, as assessed by the Committee, and on securing IRB approval by the responsible investigator.

– Scan Time Request

Before scanning, a scan time request form must be submitted to the MRI Review Committee.

This scan time request is intended to update the project description and formally make a request for scan time. Before scan time is granted, several assurances regarding safety and policy adherence need to be reviewed by the appropriate committees. This form includes name of the study, project description, study details, special requirements, and list of equipment used. The request must be accompanied by a copy of the IRB approval and consent forms. The proposal also must include the names of any personnel involved in obtaining MR data, and their qualification to run the study.

The proposal must provide the sequence parameters and tech instructions.

Non-UM Researchers must also have a current Facility Use Agreement with the University of Miami.

IRB Approval for Research protocols

Each investigator is responsible for obtaining IRB approval for his/her study and for filing the approval document with the facility. Under no circumstances will an investigator be allowed to use the facility without submitting proof of IRB approval.

Informed Consent

Investigators are also responsible for explaining informed consent/assent procedures to every subject and for having every subject sign the informed consent/assent forms. No subject can be scanned without valid informed consent/assent forms having been signed. The signed consent/assent forms must be presented prior to the scan being performed.

The consent form for any study involving the imaging facility must include mandatory language for all neuroimaging studies. This language is included below.

“This procedure involves a magnetic resonance imaging (MRI) scan. MRI is an imaging procedure which uses a very strong magnetic field and radio waves to take cross-sectional images of your brain. Absolutely no x-rays are used to produce the image.

People are at risk for injury from the MRI magnet if they have certain types of metal in their bodies. Participants will be screened for and asked about these conditions before having each scan, and if they have any, they will not receive an MRI scan. Items that may cause harm include pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, piercings, implanted delivery pumps, or shrapnel fragments. Welders and metal workers are also at risk for injury because of possible small metal fragments in their eyes of which they may be unaware. In addition, all magnetic objects (for example, watches, cell phones, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

Pregnant participants will not be scanned. Although there are no known risks associated with MRI during pregnancy, according to facility policy, UM will not scan someone who is pregnant. Therefore, all women of childbearing potential (menstruating or >12 years old) must complete a form stating that they are not pregnant within 24 hours of each MRI scan.

Everyone having an MRI scan will be fitted with hearing protection. Participants will be asked to wear earplugs or headphones to muffle the sound. The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss.

Sometimes, people report being uncomfortable during an MRI scan. For example, people with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. Because of the strong magnetic field, some people might have brief periods of muscle twitching, eye discomfort, dizziness, mild nausea, headache, or a sensation of flashing lights. Participants will be informed that the best way to minimize these events is to not clasp one's hands together and not cross one's legs during scanning. Should discomfort arise, participants may stop the scan at any time and for any reason.

The imaging facility is a research facility, not a medical facility. The MRI scans obtained at the imaging facility are research scans, to be used for scientific purposes. The scientists who review the scans are not physicians and they have no competence in evaluating the scans for medical or

therapeutic purposes. These scans are not meant to provide clinical or diagnostic information. Moreover, the facility has no medical staff to provide clinical information or advice. If you are worried or have any concerns about anything that a scan might reveal, you should talk to your doctor about it or otherwise seek medical attention.

Although not routine, a small proportion of research scans may be read by a radiologist. If any results of clinical significance are found, we will communicate this information to you. We may recommend that you seek advice from your primary physician or a specialist. The University of Miami will not pay for any costs relating to your standard medical care. You or your insurance company will be responsible for such costs. Should your scan be part of this small sample, receiving medical information may cause you some distress.

There are no known long-term risks of MRI scans.

You may ask and will receive answers to any questions during the course of the scanning procedure.”

Privacy

Subjects to be scanned in the Imaging Facility are given unique identifier. No actual name nor any other identifying information is to be entered in the MR computer file, to make certain that subject privacy can be fully observed. Individual investigators are responsible for keeping records in order to identify the raw data collected in the Facility.

Safety screening

A MR safety screening will also be administered by Facility staff. Prior to any procedures, the safety screening will be signed by the person providing informed consent (individual or parent) and by the MR personnel performing the screening. The screening results, or any question regarding safety, may preclude a subject from participating in a study. This screening will be filed in the MRI facility and a copy of the MRI screening will be given to the investigator.

For subjects with a history of cerebro-vascular disease, neurosurgical procedures, or accidents, in connection with which metallic objects or particles might have been lodged inside soft tissue of brain or eye, it is necessary to submit a medical report, signed by a physician, stating that it is safe for the subject to undergo MRI. This report needs to be filed together with the signed IRB and screening questionnaire.

Pregnancy

Female subjects must not be pregnant to complete an MRI scan. All women of childbearing potential (menstruating or >12 years old) must complete a form stating that they are not pregnant within 24 hours prior to each MRI scan. If the individual is under 18, the parent/legal guardian will complete the form.

Incidental findings

The Imaging Facility is a research facility which is part of the University of Miami's College of Arts and Sciences. MRI scans are conducted for research purposes only and not used for diagnostic or therapeutic purposes. Occasional variations from expected brain morphology can be seen in the MRI scans from research participants. Variations from normal morphology may or may not have medical implications. The Imaging Facility does not have medical or radiological staff to interpret MRI scans. All subjects must be made aware that research staff do not have the requisite expertise to identify interpret or communicate neurological findings for diagnosis or treatment. Under no circumstances may an investigator, research staff, or the imaging facility staff interpret scans as normal or abnormal. The Imaging Facility will **not** be involved in any medical interaction with the subject.

Although not routine, a small proportion of research scans may be read by a radiologist. In the event a non-clinician makes an observation that seems to have clinical significance, the team will request a consultation from a radiologist at the Miller School of Medicine.

The Imaging Facility will keep records of the Radiologist Report detailing the consultation findings which will be forwarded to the principal investigator of the study via email. The principal investigator is responsible for contacting the subject with any pertinent findings, maintaining adequate records of release documentation, and reporting to IRB.

V. FEE STRUCTURE

Funded research with UM accounts: A fee of \$500.00 per hour is charged for funded research for studies performed during the Facility's business hours. For studies that require less than one hour of time in the scan suite, the \$250 fee will be prorated based on 30-minute increments.

Funded research with non-UM accounts would need to have an approved Facility-Use Agreement or will be charged the unit cost plus the University of Miami established F&A rate.

If scans are cancelled with less than 3 business days' notice, a cancellation fee will be assessed.