FAU
FLORIDA ATLANTIC UNIVERSITY

MRI and fMRI in Human Subjects Research

Guidance for FAU Faculty, Staff & Students

1 OVERVIEW

The evolution of MRI technology from clinical to academic settings raises questions about how to protect the safety of research participants without impeding important research. Several organizations, such as the National Institute of Mental Health (NIMH) and the American College of Radiology (ACR) have taken the lead in addressing this important issue. To ensure that MRI research at Florida Atlantic University at the new FAU MRI Facility meets the highest ethical and safety parameters, the FAU IRBs have provided this summary of the organizations' key recommendations for developing protocols. The goal of this document is to inform researchers about the unique safety concerns of using MRI in human subjects' research. This document is a guideline for writing protocols involving MRI or fMRI for researchers to submit for IRB review.

IMPORTANT: Approval of the FAU MRI Safety Committee must be obtained prior to submission to the FAU IRB in order to confirm MRI related scientific merit of the proposed research, acknowledgment that the study requirements can be performed at the FAU MRI facility, and determination of appropriate coordination requirements by the research team

2 PREPARING THE IRB SUBMISSION

When preparing your IRB submission, use the following regarding MRI use and safety into your overall research protocol:

2.1 PATIENT/SUBJECT SCREENING: SINGLE MOST IMPORTANT SAFETY STEP

PLEASE INCLUDE THE FOLLOWING INFORMATION IN YOUR IRB PROTOCOL

Location

Magnetic Resonance Imaging (MRI) and Functional Magnetic Resonance Imaging (fMRI) will be conducted at the FAU MRI Facility located on the Boca Raton campus at ME104.

Medical assessment procedures

Structured medical and neurological histories, a standardized review of systems, and baseline laboratory values may be obtained as necessary to assess that subjects meet inclusion and exclusion criteria.

General Subject Exclusion Criteria for MRI

1. Any medical conditions that may interfere with brain function relevant to the study as determined by the PI.
2. Subject is unable or unwilling to lie still in the scanner (i.e. due to claustrophobia or weight)
3. Subject has metal in their body or other reason that they cannot undergo magnetic resonance imaging (subjects must complete the metal screening with study personnel to confirm if they are eligible to participate)
4. [[FOR BRAIN IMAGING]] Previous brain surgery or intracranial abnormalities they may complicate interpretation of the brain scans (e.g., stroke, tumor, vascular abnormality).
5. [[FOR BRAIN IMAGING]] Currently taking medication that might affect brain function as per the P.I. (i.e. antidepressants, antipsychotics, anxiolytics, benzodiazepines, sedatives, anti-seizure medications)
6. [[FOR BODY IMAGING]] Previous surgical procedure in the body that might complicate interpretation of the MRI scan results of that body part.
7. [[FOR BODY IMAGING]] Currently taking medication that might affect body functions as per the P.I. (i.e. medications that affect the heart or autonomic nervous system, GI tract, lungs, etc.)
8. Pregnancy (a negative pregnancy test is required if the subject is uncertain of pregnancy status)
9. Concurrent participation in another research protocol that might affect the outcome of this study.
10. Use of a defibrillator or pacemaker or other implanted or metallic electronic device. Doing so could cause electric shock, burns, electrical interference, or death.
11. History of Seizures

PLEASE INCLUDE THE FOLLOWING IN THE RISKS SECTION OF THE IRB PROTOCOL

MRI Risk:

The MRI scanner is essentially a large magnet that has not been shown to have direct effects on the physiological function of the brain or body. The MRI scan does not involve any radiation exposure. Due to the strength of the magnetic field of the MRI, there is a risk of being injured by receiving a burn on your skin or if an unsecured metal object flies into the MRI scanner. In order to minimize this risk, subjects will be asked to remove all metal objects from their person. Also, all metal objects will be cleared from the area prior to the scan. This is the standard practice when patients undergo MRI exams. It is important when discussing the study that subjects inform the staff if they have any of the following metal objects in their body that might be a contraindication to undergoing MRI scanning:

- Surgically implanted electrical or mechanical devices (e.g. pumps, stents, stimulators, etc.)

- Pacemaker
- Surgically placed metallic clips (aneurysm clips)
- Orthopedic hardware
- Ear implants
- Any history of metal fragments in the eye

Subjects may be participating in other studies for research or medical purposes, however, they must inform the investigators of their participation in other studies.

- MRI screening will be performed by study or MRI personnel and confirmed by MRI personnel at the time of the scan.
- If screening reveals there are “minor" contraindications[1] to having an MRI, inform the participants about these risks during the consent process. This may also be performed by the MRMD.
- Clarify if repeat scans are planned with the participant (e.g., daily or weekly for some period of time). If so, discuss how you will screen for MRI risk factors prior to each scan. Subjects need to undergo subsequent metal screening at each time point to ensure there are no changes in their health that would prevent them from undergoing the MRI scan.
- Describe how the investigators entering the scanning room will be screened.

All study personnel that might be entering the MRI facility must undergo Level I MRI safety training. If they are going to be in the MRI control room, they must also complete an MRI screening form with a member of the MRI facility staff to confirm that there are no contraindications to being in the scanner facility. The screening forms for the study personnel will be kept in the MRI facility. Study personnel will notify the MRI staff of any changes in their health status, and particularly any surgical procedures that might have included metal objects/devices placed in the body. Otherwise, the screening form will be completed on a yearly basis.

2.2 Emergency Procedures

- Emergency procedures will be managed according to the standard operating procedures of the FAU MRI facility.

2.3 Data Analysis, Confidentiality & Privacy

- Since personal images (some with incidental findings) and screening tools (with sensitive medical information) will be collected, specify in the **Research Materials, Records, and Privacy** section of the protocol what will be done to protect participants’ privacy and confidentiality. Will a coding system be used? What types of password protection and encryption will be used for electronic data? If research

[1] A "minor" contraindication is one which is unlikely to pose a risk, but which may, if not carefully monitored, result in injury. (E.g., tattoo may be at minor risk for burns).

documents will be physically stored in paper form, how will they be secured and how will they be destroyed once no longer needed?

- Provide an overview of how the MRI scans will be analyzed. For example, for brain MRI scans, images may be analyzed utilizing one of several semiautomated method such as statistical parametric mapping (SPM) or a region/seed based analysis approach. These analysis approaches assess differences between scan states and study groups. MRI scans will potentially be assessed for several measures such as cerebral blood flow, blood oxygenation level, functional connectivity and brain volumes.

2.4 Incidental Findings

INCLUDE THIS LANGUAGE IN THE RISK SECTION OF THE IRB PROTOCOL

Incidental Findings: Any abnormal incidental findings from the scans or other procedures may cause additional stress and/or anxiety in the subjects. However, the incidental findings will be discussed with the subject by the study PI or a designated physician such as the MRMD. The subject will be counseled on the findings and provided information on how to follow up with his or her neurologist or primary care physician. Any information will be made available to the subject's primary care physician so that it can be properly addressed.

2.5 Informed Consent For a Research MRI

The consent form and informed consent process for a study involving MRI scanning should include the materials provided on the example consent form. Full consent for the protocol is the responsibility of the research team. There is a separate screening form that will be completed by each subject on the day that they undergo the MRI scan itself. This does include acknowledgement that they understand the main risks of the MRI scanner and the MRI scanning environment. They will also confirm that they do not have metal or other issues that would potentially prevent them from undergoing an MRI scan as per the study PI or the MRMD.

2.6 Recruitment

In the research proposal, in addition to inclusion/exclusion criteria for the overall study, list any conditions that would disqualify someone from having an MRI scan on relevant recruitment material such as ads, email text, etc. Inform the participant of the time commitment involved, especially if repeat scans are planned (e.g., volunteers will receive 3 MRI head scans, one per month, over 3 months).

2.7 Training

All research personnel that will be involved with the FAU MRI Facility will need to undergo at least Level I MRI safety training. If study personnel will need to be in the control room (Zone III) or the MRI room itself (Zone IV), they will need to have Level II MRI safety training. Additional training for handling research and scan related data may be required and should be noted in such cases.

2.8 SAFETY

- If screening reveals that potential participants have implants or devices that are new or that have no safety data, researchers should consult the MRMD and the MRI staff to assess the compatibility of the devices with the MRI scanner's field. If information is unavailable, participants will be excluded from study for safety reasons. www.MRIsafety.com is the official site of the Institute for Magnetic Resonance Safety, Education, and Research**.**
- *If applicable*, discuss in the same section how the PI will assess the safety and compatibility of ***external*** research devices being brought into the MRI suite (such as non-FDA-approved devices developed for research, or devices for displaying stimuli or recording behavioral responses from the participant.) Provide a description of these devices and procedures for evaluating their safety; indicate what technical consultants (e.g., a biomedical engineer) have evaluated the safety of these devices in terms of magnet exposure, burn, and fire risk.

2.9 VULNERABLE POPULATIONS:

- In the Informed Consent Process section of the protocol, discuss what additional safeguards will be put in place for vulnerable populations, such as children, cognitively impaired, etc.
- Researchers conducting studies involving children as research participants should be proactive in obtaining permission during the informed consent process to inform the child's primary care physician of any incidental findings since parents may not fully appreciate the need for follow up.
- Researchers are also advised to have a plan for how to handle and report suspected child abuse or neglect, since an MRI study may yield findings suggestive of abuse.
- Any proposed study to scan pediatric subjects should also address the special risks of high field magnets. Additionally, researchers should be sensitive to, and screen for, the presence of dental braces and retainers frequently worn by adolescents and to what extent these pose a safety issue (e.g., heating) or research issue (introducing artifacts in brain images of interest.

2.10 ADVERSE EVENT REPORTING:

In the Risks section of the protocol, discuss how unanticipated problems involving risk to subjects or others will be handled and reported. Under the Common Rule (45 CFR Part 46, Subpart A), an IRB must require reporting of all unanticipated problems resulting in risks to participants or others, even if there is no actual injury, as these hold implications for safety. In addition to reporting to the IRB, the PI and/or the MRI facility may be required to report adverse events to other regulatory or safety agencies.

3 EXPERIMENTAL DEVICES

For the study protocol under MRI PROCEDURES, the following should be used.

> The MRI scan will require the subject to lie quietly on the scanner table using a [special head holder surrounded by a head coil] [special body coil for the *body part*] that enables scans to be obtained of the *body part* for approximately XX minutes while in the scanner. This MRI will allow us to take a picture of the *body part* during different states. While in the MRI scanner, subjects will be asked to perform certain tasks [if tasks will be performed specify below] or movements but otherwise they will be asked to rest quietly.
>
> Additional information can also be provided in terms of specific tasks or testing that will be done while in the scanner. Specific sequences do not need to be specified.