SOP 09
General Experimental Procedures
MRI Facility
Centre for Neuroscience Studies
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SUMMARY

i. Research involving Magnetic Resonance Imaging (MRI) at high magnetic field strengths present unique hazards to both research subjects and individuals working within and around the MRI system. Consequently, the potential for serious personal injury is present due to the sheer size and strength of the static magnetic field along with the immense flexibility of the research system and associated peripheral hardware.

ii. The static magnetic field in the 3T MRI facility is always present. It is important that all those entering the facility be aware of the presence of the field, as it cannot be detected by our person in any way, i.e., magnetic fields cannot be felt, seen, or smelt.

iii. During MRI data acquisition the subject being imaged is also exposed to rapidly changing magnetic fields due to pulsed magnetic field gradients, and fields oscillating at radiofrequencies (around 128 MHz for 3 T). These time-varying fields are much weaker than the static field (up to 80 mT or 800 gauss) but create additional safety risks and all personnel working with the MRI equipment must be aware of these risks.

iv. During certain types of MRI data collection, there exists high, and therefore potentially dangerous, acoustic sound pressure levels (SPL). All those entering the facility must be made aware of this risk and be instructed as to the proper precautionary measures to be taken. Any patients, volunteers and/or research personnel present in the magnet room during an MRI experiment must wear appropriate hearing protection as outlined in SOP# 05 “General Safety Procedures”.

v. As a result of the potential for serious injury, access to the 3T MRI Facility is restricted, and requires permission. See SOP# 01 “Authorization for Access to the 3T MRI Facility”, and SOP# 02 “3T MRI Facility Visitor Approval Policy”.

vi. It is imperative that all personnel who are within and around the 3T MRI facility always keep in mind the potential safety risks, and act in accordance with the guidelines set out in the Standard Operating Procedures.
GENERAL SET UP PROCEDURE

i. All volunteers/patients must be screened for incompatible medical devices as listed in SOP# 05 “General Safety Procedures”, and according to SOP# 04 “New Protocols and Ethics Procedures” before entering the 3T MRI Facility.

ii. The Operator must register the information for a new subject at the beginning of the scan session. See SOP# 13 “System Billing Guide and Standard Rates”.

iii. All personnel entering the magnet room must have obtained authorization to access the Facility (see SOP# 01 “Authorization for Access to the 3T MRI Facility”) and must have completed a Safety Checklist: “MAGNETIC RESONANCE (MR) IMAGING SAFETY CHECKLIST FOR INDIVIDUALS”.

iv. The research volunteer must have completed a Safety Checklist: “MAGNETIC RESONANCE (MR) IMAGING SAFETY CHECKLIST FOR RESEARCH SUBJECTS” (see SOP# 05 “General Safety Procedures”), and this must have been reviewed by the PI, and then submitted to the Operator.

v. The volunteer/patient, all experimental support personnel, the operator, and anyone going into the magnet room, must remove all metallic objects from their person before crossing the 5 Gauss line as marked by the door into the magnet room. For a list of articles see SOP# 05 “General Safety Procedures”.

a. The Operator is responsible for screening all objects entering the magnet room for ferrous components.

b. All objects, not already in the magnet room, should not be brought into the magnet room, unless they are necessary for the successful execution of the experiment, and have been tested using a permanent magnet in the control room, or have been viewed and permitted for entry by the MR Manager.

vi. It is mandatory for the volunteer/patient, and all others who will be present in the magnet room during the scan session to wear hearing protection either in the form of earplugs or headphones provided by the 3T MRI Facility.

vii. It is imperative that all research support personnel present in the magnet room be aware of the responsibilities and risks associated with equipment as it is operating. This includes areas of high electrical activity and potential mechanical failure points. A safe operating distance from these designated areas must always be taken into accordance. Failure to do so could result in severe injury or death.

viii. The Operator will advance the volunteer/patient into the magnet at his/her own discretion. If the operator feels at any time that the volunteer/patient is not comfortable and may panic, s/he may refuse to advance them into the magnet and may cancel the scan session.
RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR AND RESEARCH PERSONNEL

i. The PI will ensure that, at all times, at least one researcher who is physically present in the facility during scanning has security access; see SOP# 01 “Authorization for Access to the 3T MRI Facility”.

ii. The PI will ensure that, at all times, at least one researcher who is physically present in the facility during scanning is familiar with the operation of the required peripheral equipment.

iii. It is the responsibility of the researcher to notify the Operator as soon as possible if they notice that a device is not working properly, either at the time they are in the facility or via email to the MR Manager (briend@queensu.ca) so steps can be have taken to rectify it. (See SOP #11 “MRI Equipment Handling Procedures”)

iv. Researchers are responsible for saving and then deleting behavioural data off the stimulus-delivery computers. Similarly, although they can store experimental scripts and stimuli on the stimulus-delivery computers, the integrity of these files cannot be guaranteed and so researchers should always bring these files (eg, on a CD or DVD) to their scanning session.

v. Researchers are responsible for the informed consent procedure and for reviewing the safety checklist “MAGNETIC RESONANCE (MR) IMAGING SAFETY CHECKLIST FOR RESEARCH SUBJECTS” with their volunteer (See SOP# 01 “Authorization for Access to the 3T MRI Facility”).

vi. The researcher is responsible for ensuring that their scanning session will end punctually at the specified time*. No accommodation for overtime can be made unless the operator and the researcher scheduled in the next scanning slot both agree. Overtime will be charged at the standard rate (see SOP #13, “System Billing Guide and Standard Rates”).

*Note that the end time means exiting the MR control room and having replaced all equipment to their normal operating state and not exiting the magnet room at that time.
RESPONSIBILITIES OF THE OPERATOR

i. The Operator is responsible for ensuring the physical and emotional safety of all research personnel and volunteers/patients within the magnet room. This includes wearing proper hearing protection and being made aware of the critical operating areas.

ii. The Operator is responsible for ensuring that the lead researcher is present in the facility when research studies are in progress. When data is being collected from a volunteer in the magnet at least one additional person, other than the operator, must be present in the magnet or control room.

iii. The Operator is responsible for ensuring that all necessary patient safety devices are operational for a scan session. It is at the discretion of the operator to cancel the scan session at any time if any or all of the safety devices are not operational. All patient safety devices are listed below. Not all safety devices may be necessary for all experiments.
   a. Emergency squeeze ball
   b. Audio system
   c. Cameras
   d. First-aid kit, back-board, and MR compatible gurney
   e. Fire extinguisher
   f. Smoke detector

iv. The Operator is responsible for notifying the MR Manager of any patient safety device that is not operational.

v. The Operator is responsible for notifying the MR Manager of any peripheral device that is not operational. Peripheral devices include but are not limited to:
   a. Stimulus Presentation Systems
   b. Physiological Monitoring Devices
   c. Control or Stimulus Presentation Computers
   d. Projection Screen
   e. RF Coils

vi. It is the responsibility of the Operator to screen all items entering the magnet room for ferrous components. A strong handheld magnet is made available for such testing.

vii. The Operator is responsible for placing any soiled linen in the soiled linens bin, kept beside the door inside the magnet room.

viii. The Operator is responsible for returning all peripheral devices and any other item used during the scan session, to their original holding places upon completion of the scanning session.
RESPONSIBILITIES OF THE FACILITY

i. The Facility is responsible to check all Primary devices daily. Primary devices are as follow:
   a. The magnet system
   b. All patient safety devices
   c. The Facility will inform operators and investigators of malfunctions of Primary devices, if their scan time will be affected.

ii. Secondary devices will not be checked daily. Secondary devices are all peripheral devices as listed in section 4.v. If one of these devices fails, the facility may out of courtesy inform operators and investigators. If the Facility is aware of failure of a specific secondary device that will affect upcoming scan time, the Facility will notify the appropriate operators and investigators (see SOP# 11 “MRI Equipment Handling and Procedures”).
INTRAVENOUS INJECTIONS AND CONTRAST-ENHANCED STUDIES

i. Human studies involving the injection of gadolinium-based contrast media present unique safety concerns but may be conducted under the following conditions and after acquiring the appropriate Review Ethics Board (REB) approvals (See SOP# 04 “New Protocols and Ethics Procedures”).

ii. Due to the potential for adverse reactions, a licensed and qualified physician must assume responsibility and be present during the entirety of the scan session.
   a. It is the responsibility of the Principal Investigator (PI) of the study to ensure that a qualified collaborating physician is involved. A qualified physician may be the PI if they meet these requirements.
   b. It is the responsibility of the PI and the qualified physician to procure their own gadolinium-based contrast media.
   c. The qualified physician must be the one to inject any intravenous gadolinium-based contrast media.
   d. The qualified physician is required to have the appropriate certifications for the administration of intravenous gadolinium-based contrast.
   e. It is the responsibility of the qualified physician to have appropriate emergency medication on site in case of an adverse reaction. It is also the responsibility of the qualified physician to have an emergency-care plan in place to care for a participant experiencing an adverse reaction. The qualified physician will present this plan to the MR Facility Manager and the operator and inform them of their responsibilities in the case of such an adverse reaction. The facility has procedures in place to respond to a medical emergency and these will be followed in the case of an adverse event in response to intravenous gadolinium-based contrast (See SOP #06 “Emergency Procedure”).
AUTHORIZED SIGNATURES

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