

Maryland Neuroimaging Center (MNC)

Magnetic Resonance Imaging Laboratory Standard Operating Procedures

Version 2.0, October 2016

Maryland Neuroimaging Center
University of Maryland
Avrum Gudelsky Building, #795
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Introduction

These are the Standard Operating Procedures (SOPs) for the Magnetic Resonance Imaging (MRI) facility at the Maryland Neuroimaging Center (MNC), which is part of the Neuroscience and Cognitive Science Program (NACS) at UMD. These SOPs were developed based on guidelines from the American College of Radiology (ACR). In some cases, ACR guidelines* were used verbatim, and in other cases, paraphrased. Guidelines related to the specific characteristics and operations of the MNC MRI facility were developed in-house based on the intent of the ACR guidelines. Note that the MRI facility is one component of the MNC, which will include resources for multiple imaging techniques, including EEG and MEG.

These SOPs will be reviewed annually and updated as needed. Significant procedural updates related to safety and training must be made in consultation with UMD's Department of Environmental Safety, and approved by the Institutional Review Board. The MNC Director is Dr. Luiz Pessoa. Questions regarding facility operations, or these SOPs, should be directed to Dr. Pessoa or Sandy Collier, Manager, MNC.

MRI Facility Address and Phone Number:

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* <http://onlinelibrary.wiley.com/doi/10.1002/jmri.24011/full>

Oversight of the MNC is the responsibility of the MNC Director

2.1 Role of the MNC Executive Committee: The MNC Executive Committee is responsible to help support the MNC Director as requested for the oversight of MNC operations, including facility operations, policy development and implementation, staff hiring and management, budgeting, and safety assurance and research compliance. The MNC Executive Committee reports to the Dean, College of Behavioral and Social Sciences.

2.2 Role of the MNC Internal Advisory Board: The MNC Internal Advisory Board assists the MNC Director with respect to all MNC facility operations, policy development and implementation, staff hiring and management, and safety assurance. It also advises the MNC on its service to the university. Members of the MNC Internal Advisory Board are appointed by the MNC Director. There are no set terms of service, but individuals who are major users of the MNC or are chairs of department are likely to be appointed to the Board. This allows their needs and concerns within the facility to be well represented; in addition, their expertise can be used to shape and further the goals of the MNC.

MRI Facility Personnel

Designation and Description of Magnetic Resonance (MR) Personnel and Non-MR Personnel

3.1 MNC Personnel include MR Personnel, who perform activities within the MNC (such as the MR physicist), and Non-MR Personnel, who perform other work associated with the MNC, such as an administrative assistant, as well as personnel whose research involves other techniques (e.g., MEG).

3.2 All MR Personnel must complete at least one MRI safety lecture or prerecorded presentation approved by the MNC Director. Attendance must be repeated annually and documented to confirm these ongoing safety certifications. These individuals are referred to as MR Personnel, of which there are two levels.

3.3 It is the responsibility of the MNC Director to determine which MR Personnel designations individuals may have.

3.4 A current list of MR Personnel, their levels, and the due date of their next safety training/update must be maintained within the MR facility at all times.

3.5 Level 1 MR Personnel

3.5.1 Definition. Level 1 MR Personnel are individuals who have had MR safety training as approved by the MNC Executive Committee. The designation of Level 1 MR Personnel typically applies to undergraduate and graduate research assistants, post-doctoral fellows, and research assistants from individual laboratories.

3.5.2 Facility access allowance. Level 1 MR Personnel are permitted to be in Zones 1 and 2 of the MNC alone. Level 1 MR Personnel may have keycard access to Zone 1 and Zone 2 of the MNC facility. They are not permitted to be in Zone 3 unless they are under the supervision of a Level 2 MR personnel member.

3.5.3 Documentation of Level 1 MR Personnel qualification. Documentation of Level 1 MR Personnel qualification must be recorded on the appropriate form (see Appendix B), updated at least annually, and must be signed by the MR Physicist. Records of documentation must be maintained within the MNC.

3.6 Level 2 MR Personnel

3.6.1 Definition. Level 2 MR Personnel are individuals designated as sufficiently trained to be in the MNC MRI facility (i.e., Zones 3 and 4) on their own (except when a participant is being scanned, during which time two persons are required), and to supervise Level 1 MR Personnel and visitors in the MRI facility. They are also sufficiently trained to oversee the MR screening process and give final approval for an individual to enter the magnet room and undergo imaging. Generally, these are individuals with greater experience in the MR environment than Level 1 MR Personnel. These individuals must demonstrate knowledge of the broad aspects of MR safety issues, including, for example, issues related to the potential for thermal loading or burns, and direct neuromuscular excitation from rapidly changing gradients. They must also demonstrate specific knowledge regarding the safety procedures within the MNC.

3.6.2 Facility access allowance. Level 2 MR Personnel are permitted to be in the MRI facility unsupervised and to supervise Level 1 MR Personnel when they are in Zone 3 or Zone 4 of the facility. Level 2 MR Personnel may be permitted keycard access Zone 3.

3.6.3 Documentation of Level 2 MR Personnel qualification. Documentation of Level 2 MR Personnel qualification must be recorded on the appropriate form (see Appendix B), re-certified annually, and must be signed off by the MR Physicist. Records of documentation must be maintained within the MNC.

3.7 MRI Operators

3.7.1 Definition. MRI Operators are Level 2 MR Personnel who have undergone training to operate the Siemens 3T TIM Trio System and who have been approved as MRI facility Operators by the MR Physicist.

3.7.2 Facility access allowance. As Level 2 MR Personnel, MRI Operators are permitted to be in the MNC alone (except when a participant is being scanned, during which time two persons are required) and to supervise Level 1 MR Personnel when they are in the facility. Level 2 MR Personnel are permitted keycard access to the MNC.

3.7.3 Documentation of MRI Operator qualification. Documentation of MRI Operator qualification must be recorded on the appropriate form (see Appendix B), updated at least annually, and must be signed by the MR Physicist. Records of documentation must be maintained within the MNC.

3.7.4 Training for MR Operators is described in Section 10.

MNC Researcher

4.1.1 Definition. MNC Researchers are individuals who have had basic training concerning the use of the MNC facility as approved by the MNC Director. The designation of MNC Researcher typically applies to users of the MNC who use techniques other than MRI. These researchers need to have basic safety training so as to know general safety issues associated with the use of the MNC. But, because they are not engaged in MRI research, MNC Researchers are not required to have the type of knowledge required of Level 1 or Level 2 MR Personnel.

4.1.2 Facility access allowance. MNC Researchers are permitted to be in Zones 1 and 2 of the MNC. They are not permitted to be in Zone 3 unless they are under the supervision of a Level 2 MR personnel member.

4.1.3 Documentation of MNC Researcher qualification. Documentation of MNC Researcher qualification must be recorded on the appropriate form (see Appendix B), updated at least annually, and must be signed by the MNC Director. Records of documentation must be maintained within the MNC.

4.2 Non-MR Personnel

4.2.1 Definition. Non-MR Personnel include individuals who are associated with the MNC but who do not work within the MNC itself. These include administrative assistants, research assistants, and others who work with the MNC, but have not undergone safety training. Non-MR Personnel must be escorted within the MNC by MR Personnel with at least Level 1 certification. These individuals will not enter the magnet room (room 1157A) without safety screening.

4.2.2 Facility access allowance. Non-MR Personnel are not permitted to be in the MNC alone or to have keycard access to the MNC.

4.2.3 Documentation is not required for Non-MR Personnel.

4.3 Visitors (MRI Participants and their escorts)

4.3.1 Definition. Visitors to the MNC that are study participants or escorts of those participants (e.g. in the cases where the participants are minors (under 18 years of age) or clinical populations).

4.3.2 Facility access allowance. Visitors are not permitted to be anywhere inside the MNC without supervision by MR Personnel with at least Level 1 certification. All scans with minors and clinical populations are required to have 3 trained MR Personnel (operator plus two others with at least Level 1 certification) in the Control Room / MR Room during the scan (while the participant is in the Control Room / MR Room). All Escorts (Parent, Guardian, other Relative), need to be safety screened in case they need to enter the MR Room. If not screened, they cannot enter the MR room, and the associated MR Personnel are informed that the escort should not enter the MR Room. All minors and/or escorts in the MNC facility MUST be supervised at all times by someone with at least Level 1 training. Older minors who can drive themselves to the facility must still be escorted by their parent or guardian, whether for a scan or behavioral study. All parents, guardians, and escorts of minors or clinical populations must remain in the building and supervised by a Level 1 personnel at all times.

Facility Description

5.1 The MNC is located in the Avrum Gudelsky Building #795 on Greenmead Drive, at the University of Maryland, College Park. It consists of approximately 6000 sq. feet including officesuites, workspace, and conference rooms. It also includes a behavioral testing suite, EEG test suite, MEG facility, and training and classroom space.

5.2 There are five key-card accessible doors in the MNC: the front door to the building; the entrance from the main reception area to corridor 1198, Zone 1; the entrance to the corridor that houses the MR Reception area, corridor 1197; the entrance to room 1157; and the entrance to the Equipment Room 1153 (zone 3). Rooms 1157 (Control Room) and 1157a (MRI machine) are Zones 3 and Zone 4, respectively. This part of the MNC has key-card accessible locked entrances from the MNC hallway 1197. This latter doorway is at the end of a corridor 1198, part of Zone 1, and has several doors into other parts of the MNC. Key card-access to this part of the MNC is possible for Level 2 MR Personnel. The room descriptions for this restricted access part of the MNC appear below:

Hallway 1197 (Zone 2):

Room 1159: Restroom

Room 1153: MRI equipment room (Zone 3)

Suite 1161 is the MR Facility Reception area including (Zone 2):

Room 1161A: Dressing/Changing room

Room 1161B: Mock Scanner Room

Room 1161C: Interview and Testing/Training Room

Room 1161D: Waiting Room

Room 1161E: Storage Closet

Suite 1157 includes (Zone 3 and 4):

The Control room for the MRI scanner is 1157, Zone 3. Room 1157A holds the Siemens 3 Tesla MRI scanner, Zone 4.

5.3 The MR Physicist has an office in 1104C. The MR Technologist has an office in 1109. The Manager has an office in 1104A. These are in zone 1.

5.4 Room 1107 is the Neuroimaging Data Analysis Lab which consists of a meeting space and data analysis computers. This room is in Zone 1.

5.5 Room 1111 is home to the MNC faculty. This room is in Zone 1.

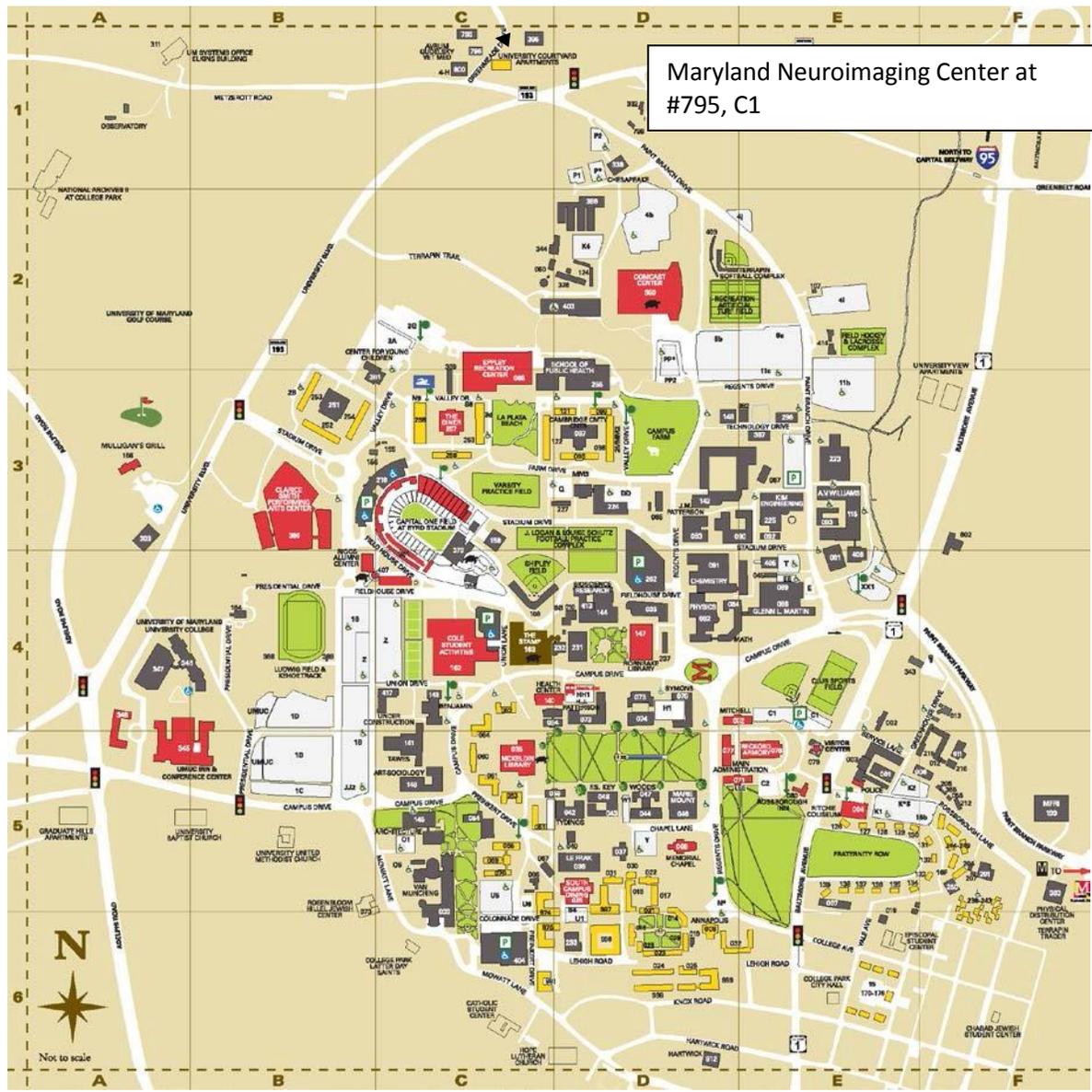
5.6 Suite 1115 (1115, 1115a and 1115b) is the Behavioral Testing/EEG suite. This area houses the EEG system. MNC facility users who acquire EEG data will have access to this room. This room is in Zone 1.

5.7 Room 1120 is the Center for Advanced Study of Language (CASL) Lab. This space is restricted to CASL personnel only. This room is in Zone 2.

5.8 Schematic diagrams of the MNC: The location of the facility in the Avrum Gudelsky Building, #795, and the layout of the MNCs MR Suite and other components are illustrated on the next page:

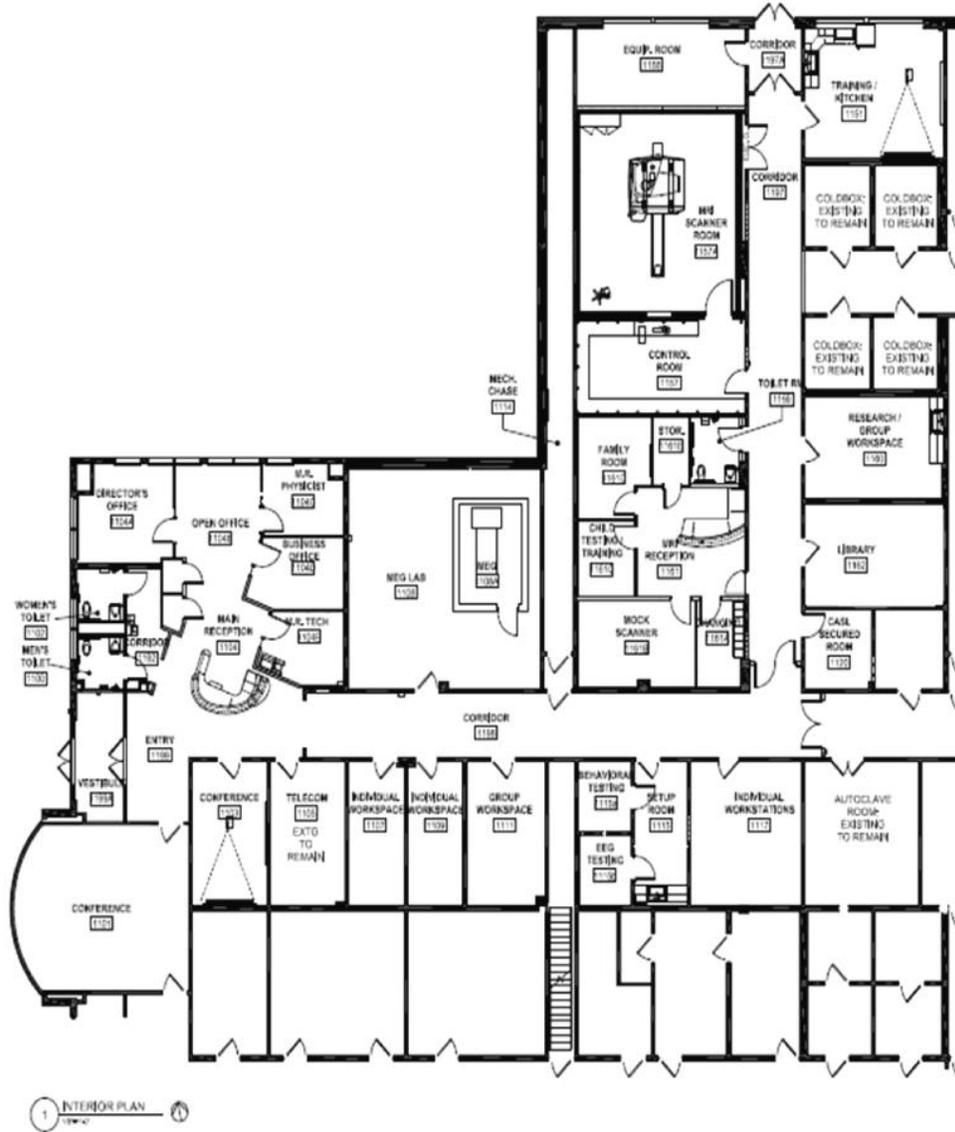
View of Outside of Avrum Gudelsky Building, #795 & Maryland Neuroimaging Center is left half of Building





Maryland Neuroimaging Center at #795, C1

The Maryland Neuroimaging Center





The footprint of the entire MNC consists of a restricted access area (MRI facility with arrows depicting the two entrances to the MRI facility), as well as other areas which house the Mock MRI scannersuite, neuroimaging data analysis suite, Behavioral/EEG laboratory and MEG.

MNC Zoning and Access

- 6.1 Zoning. For the purpose of safety, the MNC is considered to have four zones (as specified by the ACR guidelines).
 - 6.1.1 Zone 1 is the Main Reception and front office area of the MNC including entry 1199 and rooms 1104A-1104E. Zone 1 includes corridor 1198 directly outside the Main Reception and Front office area of the MNC and includes rooms 1107 (data analysis room), 1108 (MEG lab), 1109 (MR technologist office), 1111 (MNC faculty office) and 1117 (group workspace), and the EEG/ Behavioral testing lab in rooms 1115, 1115a, and 1115b.
 - 6.1.2 Zone 2 begins at corridor 1197 and includes the MR Reception area 1161 -1161E and the restroom 1159, training room 1151, lab rooms 1160 and 1164, library 1162, and the CASL Room, 1120
 - 6.1.3 Zone 3 is the control room 1157 and the equipment room 1153.
 - 6.1.4 Zone 4 is Room 1157a MRI magnet room.
- 6.2 Unescorted access: To have unescorted access to Zone 3, individuals must be Level 2 MR personnel. To have unescorted access to Zone 2, individuals must be Level 1 MR personnel or certified MNC Researchers.
 - 6.2.1 MNC Rooms 1157, 1157A and 1153 are physically restricted from general public access using door locks which can be accessed by keycard or a key. The outer door is spring-loaded and closes automatically after entry.
 - 6.2.2 The only individuals with unrestricted access by key to the MNC are: the MNC Director, the MR Physicist, the MNC Manager, and MR technologist, and operators.
 - 6.2.3 Level 2 MRI personnel may have keycard access to the entire MNC MRI facility, except for room 1153 (the equipment room).

Safety Procedures

(Developed based on ACR White Papers 2002, 2004 & MR Safety Guidelines 2007)

7.1 Pregnancy-Related Issues

In keeping with current ACR guidelines, pregnant MR personnel are permitted to continue working in all areas of the MNC throughout their pregnancies. Acceptable activities include, but are not limited to, positioning individuals within the scanner, imaging, entering Zone 4 in the case of an emergency. Pregnant MR personnel should NOT be present within Zone 4 while imaging is in progress.

7.1.1 ACR guidelines permit pregnant women to undergo MR imaging. However, pregnant women will NOT undergo imaging at the MNC.

7.2 Safety concerns related to minors

7.2.1 Although permitted by ACR guidelines, minors who are research volunteers will not be sedated for MRI at the MNC.

7.2.2 Minors should either wear scrubs before entering Zone 4, or have their pockets checked by Level 2 MR personnel, either manually or with a metal detector, prior to entering Zone 4. Prior to bringing personal objects such as stuffed toys into Zone 4, these objects must be checked for ferromagnetic content with the metal detector.

7.2.3 Because minors may be unreliable historians, children must be screened in conjunction with their parents or guardians. Some minors may have tattoos or ferromagnetic jewelry or makeup that their parents do not know about, and therefore should be questioned separately from parents. As a rough guideline, children aged 10–17 will be screened both with their parents or guardians and separately to ensure an accurate account of safety prior to entering Zone 4. Minors younger than 10 years old will be screened with their parents or guardians.

7.3 All scans with minors and clinical populations are required to have 3 trained MR Personnel (operator plus 2 MR Personnel with at least Level 1 certification) in the Control Room/MR Room during the scan (while the participant is in the Control Room/MR Room). All Escorts (Parents, Guardians, other Relatives) need to be safety screened in case they need to enter the MR Room. If not screened, they cannot enter the MR room, and all associated MR Personnel are informed that the escort should not enter the MR Room (Zone 4).

7.4 Auditory considerations

7.4.1 Research participants, patients, and anyone accompanying these individuals in Zone 4 during imaging must wear hearing protection. These must be in place prior to initiating any MR sequences.

7.5 Thermal issues

7.5.1 General issues: The body temperature increases if the participant absorbs more energy per unit of time than can be dissipated through thermoregulation (increased perspiration and blood flow). During the MR examination, patients may experience heat sensations on the skin and may begin to perspire. Their pulse rates may increase as well. The effects vary from patient to patient. The intensity of these effects depends on the measurement program selected. Following the examination, the body will cool off and the pulse rate will return to normal. The increase in core body temperature is usually well below 1 degree during the course of the MR examination if the

Specific Absorption Rate limits are maintained.

7.5.2 Specific Absorption Rate (SAR)

7.5.2.1 Definition: A quantity that describes how much electromagnetic energy is absorbed by the body over time, typically expressed in units of watts per kilogram. SAR depends upon the pulse sequence and the size, geometry, and conductivity of the absorbing object.

7.5.2.2 Possible adverse effects: A high local SAR may result in RF burns. A high SAR evenly distributed across the entire body exerts stress on the patients' cardiovascular and thermoregulation system.

7.5.2.3 Protection against risk: SAR is limited in MRI studies to minimize body temperature increases. Accurately determining SAR is difficult; it depends upon heat conduction and body geometry as well as upon the blood flow changes, as well as the type of imaging sequence and its parameters. The Siemens 3T system requires the participant's weight and birth date to be input when setting up the participant. It uses those two measures to calculate an appropriate SAR. If the SAR is too high for a given set of user-specified parameters, a message appears on the computer interface of the system indicating that it will not allow the image sequence with those parameters. As further protection against risk, participants should be asked about their comfort level during the session.

7.5.3 Individuals with electrically conductive materials

7.5.3.1 Individuals with electrically conductive materials in their bodies, such as wires, leads, or implants will not be imaged in the MRI scanner due to thermal or voltage dangers relating to the presence of a strong, rapidly varying magnetic field.

7.5.4 Individuals with tattoos that have ferromagnetic properties may be imaged as long as care is taken to keep the affected area thermally insulated (using pads, ice packs, etc). It is also advisable to keep the affected area as far as possible from the inner walls of the MR scanner bore. Individuals whose tattoos are less than 48 hours old should not be scanned as it may cause the tattoo edges to run, although this presents no additional physical danger to the person in the magnet.

7.5.5 Conductive Loops

7.5.5.1 Description: Having ones hands or legs in contact can form an electrical current loop. Skin to skin contact from hands to legs or touching knees together is another form of a conductive loop.

7.5.5.2 Possible adverse events: Although unlikely, local burns could result from this type of body position. The most general result is a feeling of discomfort. In some instances the participant may feel as though their arms or legs have "fallen asleep" or have a tingling sensation. This sensation will go away and is not permanent.

7.5.5.3 Protection against risk:

7.5.5.3.1 Avoid conductive loops problem by placing individuals on the patient bed in positions that do not form conductive loops. Furthermore, this issue must be described to the participant so that if he/she shifts positions on the patient bed, conductive loops are not created. Specifically, individuals must be instructed not to cross their arms or legs while in the magnet.

7.5.5.3.2 In addition, participants should be informed about the potential of local burns and tingling sensations to occur, and to alert the MR operator in such instances.

7.5.6 Drug delivery patches and pads: Some drug delivery patches contain metallic foil, thus increasing the risk of thermal injury. If the patch is in the volume of excitation of the transmitting RF coil, the individual must not undergo MR imaging at the MNC. If the drug delivery patch is outside of the volume of excitation of the coil, the individual can undergo imaging with an ice pack applied directly to the patch. The individual should be instructed to let the MR personnel know immediately if the patch begins to warm.

7.6 Cryogen-Related Issues

7.6.1 If anyone is in the magnet room while a quench occurs, OPEN the magnet room door immediately for ventilation or the participant has the potential to suffocate.

7.6.2 In the event of a system quench, it is imperative that all personnel, research participants, and patients be evacuated from Zone 4, the magnet room, as quickly and safely as is feasible. Site access should be immediately restricted until the arrival of Siemens equipment service personnel.

7.6.3 The sudden appearance of white clouds or fog around or above the MRI scanner indicates that cryogenic gases have vented partially or completely in the magnet room. Police, fire, and other emergency personnel should be restricted from entering the room with their axes, oxygen tanks, etc., until it can be confirmed that the magnetic field has dissipated. There may still be a considerable residual static magnetic field despite a quench or partial quench of the magnet.

7.7 Claustrophobia and anxiety

7.7.1 Individuals undergoing MR imaging will be screened for known claustrophobia and anxiety about undergoing imaging. If these individuals wish to undergo MR imaging, they will first be offered an opportunity to practice in the simulated MR environment (mock scanner). All individuals undergoing imaging are advised that they may speak to the MR personnel throughout the imaging session, or squeeze the handheld squeeze bulb to indicate that they need attention or wish to be removed from the magnet and patient bed.

7.8 Contrast Agent Safety

7.8.1 No contrast agents will be used within the MNC.

7.9 Firefighter, police, and security safety considerations: For the safety of these emergency personnel who are responding to an emergency call at the MNC, a Level 2 MR personnel should be on site if possible, prior to the arrival of the emergency responders to ensure that they do not have free access to Zone 4.

7.9.1 The MNC Director (or a Member of the MNC Operations sub-committee on Safety and Compliance) is responsible for prospectively educating the local fire marshals, firefighter association, police, and security personnel about the potential hazards of responding to emergencies in the MR suite. It should be stressed that even in a fire or other emergency, the magnetic fields may be present and fully operational. Therefore, emergency personnel with air tanks, axes, crowbars, or other firefighting equipment, as well as guns, etc., cannot be given free access to Zone 4. Such access might prove catastrophic or even lethal to those responding or others in the vicinity.

7.9.2 In addition to training, emergency personnel will also be provided with documents providing information about the facility and safety issues (see Appendix F).

7.9.3 The MNC has an MR-safe fire extinguisher that is located in the control room (1157) just

outside the MRI room. Also for fire safety, there is a smoke detector system and a sprinkler system that will be automatically activated in case of smoke or fire, respectively.

7.9.4 If there is a fire requiring firefighters or other emergency personnel to enter the MR facility with non-MR safe equipment, either Zone 4 must remain locked or off limits, or a decision to quench the magnet should be very seriously considered. This decision should be made if needed to protect the health and lives of the responders and other persons present. Should a planned quench be performed, Level 2 MR personnel must ensure that all emergency personnel and unscreened individuals continue to be restricted from Zone 4 until the static field is no longer detectable or at least sufficiently attenuated such that it no longer presents hazardous conditions to persons with ferromagnetic objects, such as axes or oxygen tanks.

7.10 Power outage considerations.

7.10.1 In the event of power outage, Level 2 MR Personnel who are operators must be able to release the scanner table so that it can be mechanically pulled out if the emergency power system fails to initiate.

7.10.2 Because power outages have implications for several aspects of system function, they should be reported to the MR Physicist as soon as possible. If a power outage lasts longer than 30 seconds, any ongoing scans will be stopped immediately so that the scanner can be safely shut down during the remaining time. The MRI scanner is connected to an Uninterrupted Power Supply unit (UPS) located in the equipment room 1153. The UPS can provide up to 15 minutes of emergency power during normal scanner operation. It can prevent scanner malfunction during brown-outs, voltage spikes, and very short power outages.

Safety Screening for individuals entering Zone 4 (Magnet Room)

8.1 The Screening Protocol and IRB approved screening forms are included as Appendix D.

8.2 The purpose of safety screening is to ensure that no one enters the magnet room with ferromagnetic objects, either in their bodies, on their bodies, or as part of any materials or equipment that is being brought into the magnet room. Safety screening of ALL individuals entering the magnet room is a cornerstone of keeping the MRI environment safe.

8.3 A formal screening protocol is in place for the MNC, and was developed with the guidance of ACR materials. The procedure and documentation forms are approved by the Institutional Review Board (IRB).

8.4 In keeping with the recommendations of the ACR, the magnetic safety screening is essentially the same for all individuals entering Zone 4. Individuals undergoing imaging must answer additional questions, such as height and weight. Such questions are relevant to safety issues, such as specific absorption rate (SAR), or to the presence of objects that may affect the quality of the images or the participant's comfort during imaging.

8.5 MNC staff and all MR personnel must undergo MR Safety Screening as part of their employment process and/or prior to beginning research training or work in Zone 4. MR personnel are not required to be screened prior to each and every entry into Zone 4. However, MR personnel must immediately report to the MNC Director any trauma, procedure, or surgery they undergo during employment in which a ferromagnetic metallic object or device may have been introduced within or onto them. At such a time, the employee will be re-screened to determine if any safety issues prevent him/her from safely working in Zone 4.

8.6 Completed screening forms are stored in a locked file cabinet within Zone 3 of the MNC.

8.7 Research participants must be fully safety screened prior to entering Zone 4 at every session, which includes administration of the MR Safety Questionnaire and screening for ferromagnetic personal belongings and devices on them or in them, such as watches, jewelry, pagers, and cell phones.

8.7.1 Metal detectors are not to be used as a substitute for careful screening, but may be used in the screening process by Level 2 Personnel.

8.7.2 Any individual undergoing MR imaging must remove all readily removable metallic personal belongings and devices on them, such as watches, jewelry, pagers, cell phones, body piercings, and cosmetics containing metallic particles. It is recommended that clothing items that may contain metallic fasteners, hooks, zippers, loose metallic components, or metallic threads (e.g. anti-odor clothing) be also removed or screened with a metal detector prior to entering Zone 4 to ensure that they are not ferromagnetic. Research participants and patients may wear site-supplied scrubs.

8.7.3 All individuals whose screening reveals a history of potential ferromagnetic foreign object penetration must undergo further investigation prior to being admitted into Zone 4. Examples of acceptable methods of screening include patient history, plain X-ray films, prior CT or MR studies of the questioned anatomical area, or access to written documentation of the type of implant or foreign object that may be present. After positive identification has been made as to the type of implant or foreign object that is within the patient, MR compatibility must be assessed using product labeling or Shellock MR Safety guidelines. Decisions based on published MR compatibility or safety

claims must recognize that all such claims apply to specifically tested static field and static gradient field strengths.

8.7.4 Decisions regarding whether a given participant or patient can undergo MRI in the MNC must be made by Level 2 MR personnel following criteria for acceptability predetermined by the MNC Director, and approved by the Institutional Review Board. The Level 2 MR personnel confirms this decision by signature on the participant's MR screening form.

8.7.5 If any Level 2 MR Personnel who screens a participant finds that *additional* considerations are necessary before approving the participant to enter the magnet room or undergo imaging, the case must be brought to MR Physicist or MNC Director who will make the final determination (with additional information from the potential participant or consultation with other experts as needed) about whether the participant is eligible for MR imaging in the MNC.

8.7.6 Under no circumstances will individuals be admitted into Zone 4 of the MNC if they have aneurysm clips, cardiac pacemakers, diaphragmatic pace makers, auto-defibrillators, deep brain stimulators, or other electromechanically activated devices.

8.7.7 Research participants and patients as well as their escorts (Relatives, Guardians, and Clinicians) must complete an MR safety-screening questionnaire prior to entry into Zone 3. All escorts of minors and clinical populations must remain in the facility for the duration of the visit, and must undergo this screening in case they need to enter into Zone 4.

8.7.6 There is potential for thermal injury from excessive RF power deposition. If a person undergoing MR imaging is in contact with electrically conductive material, such as a tattoo with metal particles in it, cold compresses or ice packs can be placed on the affected body area during imaging.

8.8 Device and object screening: Before an object or device is introduced into Zone 4, these objects must be tested for detectable ferromagnetic attractive forces. To do so, Level 2 MR personnel in the facility must use a strong handheld magnet (greater than or equal to 1000 G). This will allow testing for detectable ferromagnetic attractive forces. All portable metallic or partially metallic objects that are to be brought into Zone 4 must be properly identified and appropriately labeled utilizing the current FDA labeling criteria developed by ASTM (American Society for Testing and Materials) International (<http://www.astm.org>) (see the figure below).

8.8.1. The handheld magnet should not be applied to possible ferromagnetic objects that are directly attached to the human body.



U.S. Food and Drug Administration labeling criteria (developed by ASTM [American Society for Testing and Materials] International) for portable objects taken into Zone 4. The square green "MR safe" label (left) is for objects that typically do not have metallic components and that are unaffected in the presence of a large magnetic field. The triangular yellow label (middle) is for objects with an "MR-conditional" rating, and the round red label (right) is for "not MR-safe" objects. Under no circumstances should objects labeled with the red "Not MR-safe" be brought into Zone 4

Emergency Procedures

9.1 Emergency procedures must be visibly posted in the MNC, reviewed and updated as needed, and must be incorporated into safety training for all MNC Researchers and MR personnel. The current version of the emergency procedures is in Appendix E.

9.2 The major risk in the facility is related to individuals entering the MRI facility who are unfamiliar with the MRI environment and its hazards. MR personnel working in the facility must be constantly vigilant of who is entering the control room and magnet rooms. Especially in emergency situations, MR personnel must ensure that no one without proper training or screening enters the Zone 4 of the MNC (magnet room), and that those individuals who do enter have removed all ferrous material from their persons.

9.3 ALL personnel who will use the MNC must have up-to-date safety training as specified in the requirements for MR personnel. This includes basic safety training for personnel who use facilities at MNC other than MRI (MNC Researchers). These individuals must also be fully aware of the current procedures for both medical emergencies and facility emergencies.

9.3.1. Operators and level 2 personnel must participate in the annual emergency drills organized by the MNC.

9.4 There is a participant-operated squeeze bulb on the MR patient table that must be given to all research participants while they are in the scanner. Squeezing this bulb activates an audible alarm to the control room, signaling the MR personnel of any problems or discomfort the participant or patient may be experiencing. Additionally, there is a video camera mounted on one end of the magnet, providing a view in the control room of the participant or patient. There is also an intercom system in place between the control room and the magnet room so that the participant and MR personnel may communicate verbally.

9.4.1. In case the audible alarm is triggered, the MR operator on duty should stop the ongoing scan and check the status of the participant immediately. The operator will then decide if the scan session should be resumed or terminated early.

9.5 The MNC is equipped with a First Aid kit, which is located on the work bench on the left as one enters the Control Room (Room 1157). Note that the First Aid Kit itself and its contents are not MR-safe.

9.6 As part of the Zone 3 and Zone 4 restrictions, the MNC has an accessible, clearly marked, MR-safe fire extinguisher available. Additionally, there is a smoke detector system and a sprinkler system that will be automatically activated in case of smoke or fire, respectively.

9.7 During imaging activities involving research participants there must be at least one MR personnel present in addition to the MR operator for the duration that a participant is in Zone 4. This policy is in place to facilitate responses to emergencies.

9.7.1 A typical scenario would be that in addition to the participant and the MRI operator, at least one additional MR-trained person would be present in the Control Room or elsewhere in Zone 3 or Zone 4. Thus, in case of an emergency involving the participant or patient, the operator will be available to attend to the participant or patient while the other MR personnel can contact emergency personnel and meet and guide them safely within the facility.

9.7.2 In the event of Minors and Clinical populations undergoing MR imaging (Zone 4), there should be an additional person (operator and 2 MR personnel) present to oversee the needs and safety of

the participant and any visitors (if applicable) in the Control Room. A typical scenario would be that one MR personnel would be present in Zone 4 with the participant and the MR operator and other MR personnel would be present in the Control Room.

9.7.3 The only exception to the rule of having at least two MR personnel present when imaging is if (1) a volunteer who is at least Level 1 MR certified is being imaged, and (2) imaging is not part of IRB approved research. Such a situation would occur, for example, when testing equipment or pulse sequences in the MRI or scanning standard inanimate objects (phantoms) for the purpose of scanner calibration or testing. Only in this case is it acceptable for an MR operator to conduct imaging without additional MR personnel within the MNC.

9.8 Specific Emergencies and Responses

9.8.1 The following specific emergencies and responses are addressed in Appendix E: Distressed or injured individual, and facility emergencies not involving people.

9.8.1.1 In case of emergency, there are several MNC personnel designated as emergency contacts; these are listed in Appendix C. In case of emergency, at least one of these individuals should be contacted immediately.

9.8.1.2 In case of alarms sounding inside or heard from outside of the MNC, or other facility emergencies, there must be contact information for at least three responsible MNC personnel posted in visible locations within the MNC. In addition, individuals from the BSOS Dean's Office, Campus Police, Department of Environmental Safety, Facilities Management, Housekeeping and Physical Plant must be given this information to keep on file. Finally, this information should also be placed in the building's KNOX box for the use of emergency personnel.

9.8.1.3 If an MR Personnel or another person notices smoke or fire, campus 911 should be called or on a wireless device dial #3333. MNC emergency contacts should be notified immediately.

9.8.1.4 If an MR Personnel or another person notices water leaks, Facilities Management should be notified at extension x52222, and MNC Personnel should be notified.

9.8.1.5 If there is a potentially life-threatening situation, such as fire or smoke, MNC Researchers, MR Personnel and research participants, patients, and their escorts must be removed immediately from the MNC and should be escorted to a safe location outside of the building.

9.8.1.6 If it is safe and feasible, MR personnel should accompany emergency personnel into the MNC. MR personnel should take all possible steps to ensure the safety of all emergency personnel in Zone 4 (magnet room). If it is necessary for non-MR safe equipment to be introduced into the magnet room, a quench of the magnet should be very seriously considered.

9.8.2. In case of emergency, all personnel should follow the instructions of operator or Level 2 who have taken the emergency drills in MNC.

Training for Operators of the MRI Instrument

10.1 MRI operator trainees must be certified Level 2 MR personnel before beginning training to be an operator. Training of MRI operators must be approved by MR Physicist. Certification of MRI operators must be approved by the MR Physicist. This approval is documented on the form included in Appendix B.

10.2 MRI operator trainees undergo training with a certified MNC Operator. The MNC Operator training is taught by the MR Physicist and includes 12-16 hours of presentations, demonstrations and hands on training. Following the Operator Training Course the training progresses through three phases.

10.2.1 Observer phase: Trainees observe the training Operator for a minimum of 4 hours of imaging. This phase of training is meant to familiarize the trainee with operating procedures. Trainees move on the next phase at the discretion of the training Operator.

10.2.2 Assistant phase. The trainee assists the training Operator for a minimum of 10 hours of imaging, with the training Operator taking the lead. This phase of training is meant to give the trainee hands-on experience with the operating procedures, and allow them to gradually begin to perform the duties of a certified Operator. Trainees move on to the next phase at the discretion of the training Operator and MR Physicist.

10.2.3 Probation phase. Trainees operate the MRI device under the supervision of the training Operator for a minimum of 10 hours of imaging. This phase allows the trainee to build confidence in their ability to perform operating procedures, and develops the level of skill and responsibility necessary to be certified Operators. Trainees perform all operating procedures during imaging, using the training Operator as an information resource only. Trainees may apply for certification from the MR Physicist at the discretion of the training Operator.

10.3 Operators are obligated to learn updated operating techniques by attending MNC-organized trainings.

10.4 Operators agree to comply with the MNC SOPs and report any safety-related adverse events to a staff-member at the MNC during the course of their work at the MNC.

10.5 Renewal of operator status will be based on the record of the operator's safety performance in the previous 12 months. A minimum of 10 hours of operating within the last 12 months are required to guarantee high level operating skills and knowledge of emergency procedures. Renewal is also dependent upon participation of yearly emergency drills.

Appendix A-1

Documentation of Safety Training for Level 1 MR Personnel
Maryland Neuroimaging Center
University of Maryland, College Park

Name: _____

UID: _____

Department: _____

E-mail Address: _____

Phone Number: _____

UMD Position (circle): Faculty Post Doc Grad Student Staff Other: _____

Non-UMD Position (please describe): _____

Name of MNC Principal Investigator with whom your MRI research is associated: _____

Name of Safety Trainer: _____

Read Version _____ (insert version #) of the MNC Standard Operating Procedures (SOPs)

Viewed MR Safety Video _____

Attended MNC MR safety training lecture and tour _____

Passed Test for Level 1 MR personnel _____

I agree to comply with the MNC SOPs during the course of my work at the Maryland Neuroimaging Center

Signature: _____ Date: _____

I hereby confirm that this individual has successfully completed the Level 1 MR certification course at the Maryland Neuroimaging Center.

MNC Representative Signature: _____ Date: _____

Appendix A-2

Documentation of Safety Training for Level 2 MR Personnel
Maryland Neuroimaging Center
University of Maryland, College Park

Name: _____

UID: _____

Department: _____

E-mail Address: _____

Phone Number: _____

UMD Position (circle): Faculty Post Doc Grad Student Staff Other: _____

Non-UMD Position (please describe): _____

Name of MNC Principal Investigator with whom your MRI research is associated: _____

Name of Safety Trainer: _____

Read Version _____ (insert version #) of the MNC Standard Operating Procedures (SOPs)

Viewed MR Safety Video _____

Attended MNC MR safety training lecture and tour _____

Passed Test for Level 2 MR Personnel _____

I agree to comply with the MNC SOPs during the course of my work at the Maryland Neuroimaging Center

Signature: _____ Date: _____

I hereby confirm that this individual has successfully completed the requirements for Level 2 MR Certification at the Maryland Neuroimaging Center.

MNC Representative Signature: _____ Date: _____

Appendix A-3

Documentation of Operator Training for the Siemens Magnetom TIM Trio
Maryland Neuroimaging Center, University of Maryland, College Park

Name: _____

UID: _____

Home Address: _____

PI / Lab Affiliation: _____

Phone Number: _____

MNC Technologist / Operator Signature: _____ Date: _____

I agree to comply with the MNC SOPs. I agree to report any safety-related adverse events to a staff-member at the MNC during the course of my work at the MNC.

Trainee's Signature: _____ Date: _____

I hereby confirm that this individual has successfully completed the requirements to operate the Siemens Magnetom TIM Trio at the Maryland Neuroimaging Center. I will provide adequate supervision and any additional training necessary to ensure that this individual's operator skills are up to date with any changes in hardware or software in the imaging system.

MR Physicist Signature: _____ Date: _____

Appendix B

MNC Emergency Contacts (in contact order)

Dr. Wang Zhan, 301-405-3035 or 301-405-2590, wang.zhan@gmail.com, cell 443-858-4213

Christine Rebsch, 301-405-2590, rebsch.c@gmail.com, cell 301-370-4986

Sandy Collier, 301-405-4125, collier@umd.edu, cell 304-671-1176

Dr. Luiz Pessoa, 301-405-2423, pessoa.mri@gmail.com, cell 202-441-2515

Genessey Flint, 301-405-2092, gflint@umd.edu, cell 703-798-6328

MARYLAND NEUROIMAGING CENTER
MRI SAFETY SCREENING FORM
Revised 9/09/15

Appendix C

MNC Appendix D SOP Version 1.6 MR Safety Screening – RESEARCH VOLUNTEERS

Date ____/____/____

Name _____ Age _____ Height _____ Weight _____

Date of Birth ____/____/____ Male Female

Address _____ Telephone (cell) (____)____-_____

City _____ Telephone (work) (____)____-_____

State _____ Zip Code _____

1. Have you had a prior MRI at this facility? No Yes

If yes, please indicate most recent date: Date ____/____/____

2. Have you had a prior MRI elsewhere? No Yes

If yes, please indicate most recent date: Date ____/____/____

3. Have you experienced any problem related to a previous MRI examination or MR procedure? No Yes

If yes, please describe: _____

4. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? No Yes

If yes, please indicate the date and type of surgery:

Date ____/____/____ Type of surgery _____

Date ____/____/____ Type of surgery _____

5. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)? No Yes

If yes, please describe: _____

6. Have you ever done any welding, grinding or cutting of metal? No Yes

If yes, did you always wear safety protection for your eyes? No Yes

7. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? No Yes

If yes, please describe: _____

8. Have you been diagnosed with epilepsy? No Yes

9. Do you have any metallic dental work? (braces, retainer, implants, dental plates) No Yes

For female participants:

9. Date of last menstrual period: ____/____/____

10. Are you pregnant or experiencing a late menstrual period? No Yes

Appendix C

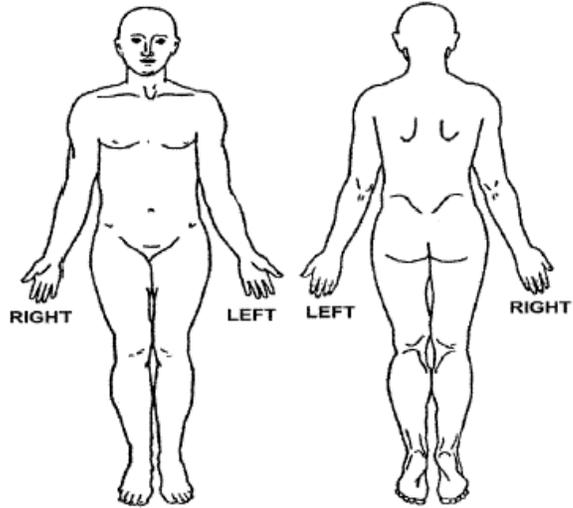


WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the MRI Technologist or Radiologist **BEFORE** entering the MR system room. The MR system magnet is **ALWAYS** on.

Please indicate if you have any of the following:

- Yes No Aneurysm Clip(s)
- Yes No Cardiac pacemaker
- Yes No Implanted cardioverter defibrillator (ICD)
- Yes No Electronic implant or device
- Yes No Neurostimulation system
- Yes No Spinal cord stimulator
- Yes No Internal electrodes or wires
- Yes No Bone growth/bone fusion stimulator
- Yes No Cochlear, otologic, or other ear implant
- Yes No Insulin or other infusion pump
- Yes No Implanted drug infusion device
- Yes No Any type of prosthesis (eye, penile, etc.)
- Yes No Heart valve prosthesis
- Yes No Eyelid spring or wire
- Yes No Artificial or prosthetic limb
- Yes No Metallic stent, filter, or coil
- Yes No Shunt (spinal or intraventricular)
- Yes No Vascular access port and/or catheter
- Yes No Radiation seeds or implants
- Yes No Swan-Ganz or thermodilution catheter
- Yes No Medication patch (Nicotine, Nitroglycerine)
- Yes No Any metallic fragment or foreign body
- Yes No Wire mesh implant
- Yes No Tissue expander (e.g., breast)
- Yes No Surgical staples, slips, or metallic sutures
- Yes No Joint replacement (hip, knee, etc.)
- Yes No Bone/joint pin, screw, nail, wire, place, etc.
- Yes No IUD, diaphragm, or pessary
- Yes No Dentures or partial plates
- Yes No Tattoo or permanent makeup
- Yes No Body piercing jewelry
- Yes No Hearing aid
(Remove before entering MR system room)
- Yes No Other implant _____
- Yes No Breathing problem or motion disorder
- Yes No Claustrophobia
- Yes No Wig or hairpiece
- Yes No Cosmetic/Colored Contacts

Please mark on the figure(s) below the location of any implant or metal inside of or on your body.



IMPORTANT INSTRUCTIONS

Before entering the MR environment or MR system room, you must remove **all** metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the MRI Technologist or Radiologist if you have any question or concern **BEFORE** you enter the MR system room.

NOTE: You may be advised or required to wear earplugs or other hearing protection during the MR procedure to prevent possible problems or hazards related to acoustic noise.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

Signature of Person Completing Form: _____ Date ____/____/____

Form Completed By: Patient Relative _____
Print Name Relationship to patient

Form Information Reviewed By: MRI Tech Level 2 Grad Student Level 2 RA Other _____

Print name Signature

Appendix D

Protocol for Ensuring Magnet Room and MR Imaging Safety Step by Step Procedures and Screening Form Maryland Neuroimaging Center

Protocol-Steps for Screening:

Screening begins with providing information regarding the safety issues within the magnet room and the importance of accurate and complete responses to the screening questions so that we can determine the safety of having the individual in the magnet room. Here's a sample script for what could be said in this process: *"The MRI machine has a very strong magnet. The magnet is so strong that it creates a forceful pull throughout the entire magnet room. Since many metal objects are magnetic, it is dangerous to bring metal objects into the magnet room. The magnet can pull some metal objects through the air into the magnet, injuring anyone in the way. Some individuals have metal in their bodies. If they enter the magnet room, the metal object inside their body may move or heat up and possibly injure the person. Thus, to ensure your safety while you are in our MRI facility, I will need to ask you safety questions. You must answer these questions completely and honestly if you wish to go into the magnet room. However, you may choose not to answer these questions and not to enter the magnet room. If you are uncertain of how to answer any of my questions, please be sure to let me know."*

After the above information is provided verbally to the person being screened, the appropriate paper questionnaire will be given to the person, which they must fill out fully. Note: Fill out questionnaire in its entirety each time the person undergoes MR imaging.

A Level 2 MR personnel conducts the screening interview. The interviewer will go through each question one-by-one to ensure that there are no safety concerns before the person enters the magnet room (Zone 4). Level 2 MR personnel are safety trained, understand the rationale for each question and are able to answer questions and address safety concerns of people entering the magnet room. Therefore, this interview cannot be performed by Level 1 MR personnel.

An important part of the interview process is to ensure that all metallic personal items are removed from the person prior to entering the magnet room. These include jewelry (wristwatches, earrings, etc.), bobby pins, barrettes, hearing aids, shoes, wallet, credit cards, and clothing with metallic fasteners or metallic thread (e.g. found in anti-odor and anti-bacterial sportswear).

Once the interview is complete, both the Level 2 MR personnel interviewer and the person being screened must sign and date the questionnaire. The questionnaire will then be filed in the locked file cabinet located in the MNC.

If a Level 2 MR Personnel who screens a participant finds that additional considerations are necessary before approving the participant to enter the magnet room or undergo imaging, the case must be brought to the MR Technologist or MR Physicist who will make the final determination about whether the participant is eligible for MR imaging in the MNC (using additional information from the potential participant, additional consultation with experts, etc., as needed).

Key Points for Safety in the Magnet Environment:

Be vigilant of who is entering the control and magnet rooms;

Individuals unfamiliar with the magnetic resonance environment and its hazards are at the greatest safety risk.

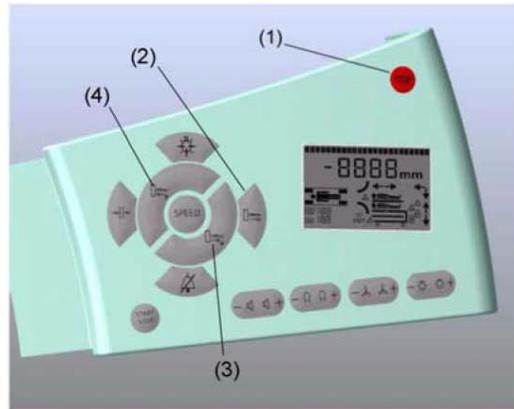
Everyone entering the magnet room, including emergency responders, must be fully screened and must remove all ferrous material from their person; and

Safety training is required of ALL personnel who will use the neuroimaging facility.

Appendix E

Response Plans for Specific Emergencies

Three (3) Types of Emergency Buttons for Different Purposes
Intercom MR Control Panel



- (1) Table Stop button
- (2) Home Position button
- (3) Table Movement Down/Outward button
- (4) Table Movement Up/Inward button

1. The Table Stop Button Press the Table Stop button immediately in case of accidents or risk of injury due to table movements (points of injury through crushing/bruising). If a table stop button is hit, the table comes to an immediate stop.

In the control room Press the red button on the top of the Intercom Console to stop the patient table movement. If it occurs in the middle of an exam, the scan is also stopped. Imaging can also be stopped using the scanner software. In the MRI instrument room, press the red button in the MR control panel.

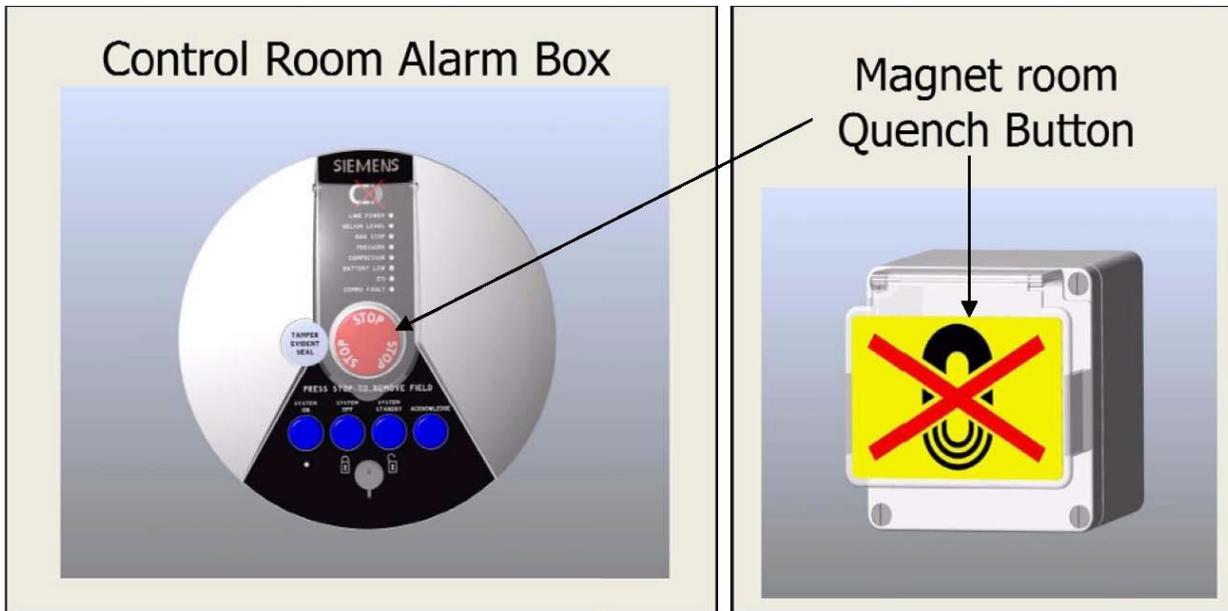
1.1. To resume normal table operation, press the Table Movement Up/Inward button and then press the Table Movement Down/Outward button. This will cancel the Table Stop. The fastest way to move the participant out of the bore is pressing the Home Position button in the MR control panel. In case of power failure or defective motorized drive, the table can be manually pulled out of the magnet bore. To do so, locate the red arrow on the patient table, pull the unlocking handle outward and upward to the end stop. The tabletop is mechanically decoupled from the motorized drive unit. Pull the tabletop out of the magnet using the handle at the foot end.



2. The Emergency Power Off (EPO) Button (3 locations, room 1157, 1157A, 1153)

- Press the EPO button to:
 - Stop all electronics associated with the MRI, including the control room computer;
 - Release the brake on the patient table.
- Two locations of the EPO buttons
 - Control Room: On the north wall, to the left of the door to the MRI Room.
 - MRI Room: On the wall, on the left after entering the room.

Appendix E Continued



3. The Quench Button

Quenching the magnet is a LAST RESORT: it is dangerous if not done properly.

- BEFORE initiating a quench, attempt to remove a person from the magnet without quenching — this is a safer alternative than an unnecessary quench.
- If you determine that quenching the magnet is the safest option, press the QUENCH button to bring down the magnetic field VERY RAPIDLY.

If a person is in the magnet room OPEN THE DOOR BEFORE QUENCH.

4. The room must be ventilated or persons inside will suffocate rapidly!

- If NO ONE is in the magnet room, quench with the DOOR CLOSED.
- CALL 911 as soon as is possible, and Siemens service 1-888-7436 (1-888-SIEM). Use Functional Location #341879
- DO NOT leave the scene. There is no danger as long as there is adequate ventilation.
- Even after the magnet has quenched, there may still be a considerable static magnetic field. Precautions must be taken for all MNC and emergency personnel entering the magnet room.

Appendix E Continued

Response Plans for Specific Emergencies

- Distressed Participant: Participant indicates distress by pressing the squeeze bulb or verbally conveying distress OR facility staff notice distress and determines that the participant must be removed rapidly from the scanner. Distress could be caused by panic attacks, claustrophobia, general fear or extreme discomfort, or a medical emergency.

Follow these steps for a participant in distress:

1. Stop imaging immediately by pressing the red button on the intercom.
2. Use the intercom to reassure the participant that you are coming in to remove them.
3. Remove the participant from the magnet room.
4. Talk with the participant in the waiting room and assess whether emergency personnel are needed; if so, call 911. Tell them the situation and give the address: Avrum Gudelsky Building, #795, 8077 Greenmead Dr. University of Maryland, College Park, MD 20742.
5. If first aid is needed, use the First Aid kit which is located on the work bench on the left as one enters the Control Room (Room 1157). Note that the First Aid Kit itself and its contents are not MR-safe
6. Monitor all emergency personnel to ensure their safety and to prevent them from introducing equipment or medical instruments, which may present safety risks, into the magnet room.

- Person Trapped in or Injured by Projectile in the Magnet:

Follow these steps:

1. Stop imaging immediately by pressing the red button on the intercom.
2. Use the intercom to reassure the participant that you are coming in to attend to them.
3. Assess whether removing the person from the magnet could lead to severe loss of blood. For example, if a person is impaled by scissors near an artery or area of large blood supply, such as in the neck, femoral region, or heart, DO NOT REMOVE THE IMPALING OBJECT as more blood loss may occur. Instead, leave the person in a stable position and let emergency responders decide the most appropriate action. Or, for example, if a person has been impaled by scissors in a hand or other extremity, consider removing the impaling object by prying it off the magnet (more than one person may be needed), and then administer first aid. If a person is trapped in the magnet or against the magnet by a ferromagnetic object, attempt to pry it off of the magnet.

If a person is trapped by the magnet or against the magnet, it may be necessary to quench the magnet so that the person can be removed. OPEN THE MAGNET ROOM DOOR FIRST!!

4. If the participant can be safely removed from the magnet environment without further injury, escort the participant to the control room and assess whether emergency personnel are needed. If so, call campus 911 or #3333 on a wireless device. Explain the situation and give them the address: Avrum Gudelsky Building, #795, 8077 Greenmead Dr. University of Maryland, College Park, MD 20742.
5. If first aid is needed, use the First Aid kit located on the work bench beside the Control Room door.
6. If emergency personnel are called, monitor them to ensure their safety and to prevent them from introducing equipment or medical instruments, which may present safety risks, into the magnet room.
7. If the participant CANNOT be safely removed from the magnet without inciting further injury, contact emergency services by calling 911. Explain the situation and give them the address:

Avrum Gudelsky Building, #795, 8077 Greenmead Dr. University of Maryland, College Park, 20742.

8. Stay in constant contact with the participant over the intercom system or by having another safety screened individual stand in the room with them. When emergency personnel arrive they **MUST** be safety screened and made to remove all ferrous objects on their person. Failure to do so may cause injury to the responding emergency personnel, other individuals present in the MRI room, and may cause further injury to the participant trapped in the MRI!
9. The MRI safe gurney is located in the MRI Instrument room and can be used as a way to safely transport participants out of the MRI environment.
10. Call Siemens service at: 1-888-7436 (1-888-SIEM), Functional Location #341879

Facility emergencies: Staff member or other person notices fire, water leaks, foreign objects in magnet with or without participant present, but no one is in grave danger. Call extension x52222.

- Call campus 911 if there is a fire.
- Remove participant if one is present.
- Attempt to contact someone from the MNC Emergency Contact List.
- Call Siemens service at: 1-888-7436 (1-888-SIEM), Functional Location #341879

Appendix F

INFORMATIONAL HANDOUT FOR EMERGENCY PERSONNEL (MARYLAND NEURIMAGING CENTER)

Located in the Avrum Gudelsky Building, #795, University of Maryland, College Park, 20742.

This document contains information for safety and emergency personnel (police, fire, EMT) about the MRI (magnetic resonance imaging) magnet in the University of Maryland, MNC located in the Avrum Gudelsky Building, #795, 8077 Greenmead Dr. College Park, MD, 20742.

The MNC is located on the left side of the Avrum Gudelsky Building, #795, attached is a drawing showing the relative location of the facility within the building.

The MNC is composed of several rooms, see attached floor plan.

These several rooms and their uses are:

Room 1161C: Interview and screening area.

Room 1161A and 1159: Dressing room and restroom.

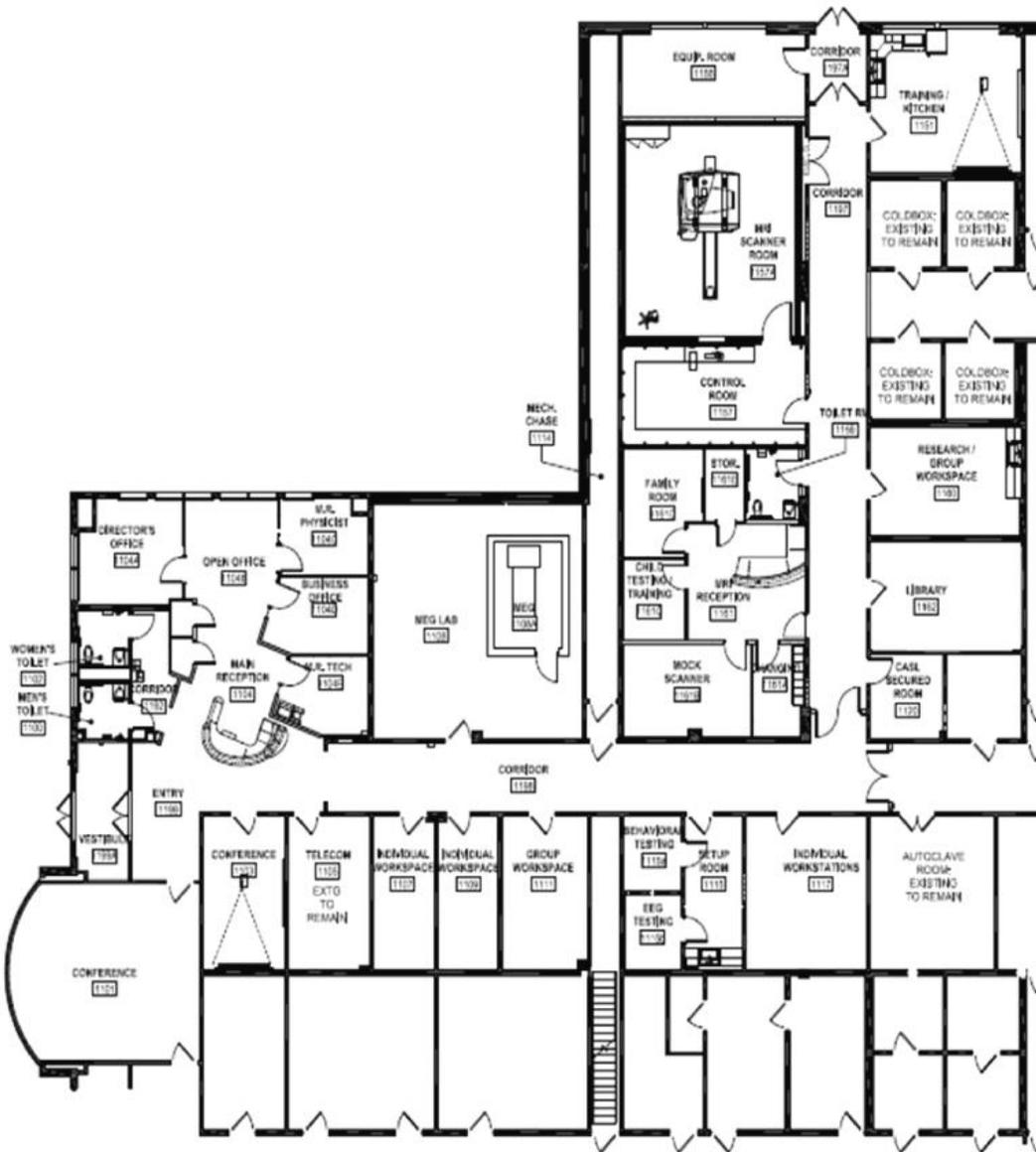
Room 1161B: The Mock MRI scanner instrument and control room.

Room 1157: Control room for MRI Scanner

Room 1157a: MRI Scanner Equipment Room

Room 1153: Equipment Room

See next page for floor plan.



1 INTERIOR PLAN

Appendix F continued

Maryland Neuroimaging Center
Informational Handout for Emergency Personnel

SOP Version 2.0

Room 1157A: The MRI magnet/scanner room.
Room 1157: The MRI control room.
Room 1153: The MRI equipment room.
Room 1115: EEG/Behavioral Laboratory.
Room 1107: Neuroimaging Data Analysis Lab.

Suite 1161 and Rooms 1157, 1157A and 1153, of the MNC house the MRI facility. This part of the MNC has key-card accessible locked entrances from the hallway. This latter doorway is at the end of a hallway which has several doors into other parts of the MNC. Key card-access to this part of the MNC is possible for Level 1 & 2 MR Personnel.

Suite 1161 houses the Mock MRI Scanner, MR Reception, Waiting Room, Changing Room and Interview and Testing room.

Room 1107 is the Neuroimaging Data Analysis Lab which consists of a data analysis meeting space which is accessible from the corridor 1198.

Suite 1115 is the EEG/Behavioral Laboratory. This area houses the EEG system. MNC facility users who acquire EEG data have been given access to this room by the Safety and Compliance Committee. The MRI-compatible EEG system is also stored in this lab on a cart which can be wheeled into the MNC's MRI control room.

Only one room in the MNC suites requires special consideration/action by emergency personnel. Room 1157A which contains the MRI magnet itself has special risks and safety precautions associated with it.

Floor plan of the MNC, arrows indicate one entrance to the MRI facility.

The MRI is a very strong magnet. This magnet is so strong that it creates a magnetic pull throughout the entire room. The magnet can actually cause some metal objects to fly through the air toward the magnet, with the potential to injure anyone in the path of the flying object. Also, if an individual who has any metal object in their body enters the magnet room it is possible for that metal object inside the body to move and possibly injure the person. **THE MAGNET IS ALWAYS ON!** No person, safety/emergency personnel or other, should enter the MRI magnet room if they have any of the following medical/surgical conditions:

- have a pacemaker or defibrillator,
- have a stent,
- have an aneurysm clip
- have been injured by a metallic object that was not removed
- have a cochlear (ear) or middle ear implant
- have had surgery involving a metallic implant (e.g. knee or hip replacement)
- have dental braces or dentures containing metal
- have body piercing (e.g. navel ring, ear rings, etc.)
- have a deep brain stimulator implant.

Appendix F continued

None of the following items should be on or be worn by any person entering the MRI magnet room:

jewelry (e.g. wristwatch, rings, necklace, etc.)
hair accessories (e.g. bobby pins, barettes, hair elastic, etc.)
wallet, credit cards
any medical objects (e.g. hearing aid, etc.)

Emergency and safety personnel should be especially mindful that absolutely no medical equipment, tools or weapons should ever enter the MRI magnet room:

ladders containing any metal
fire extinguishers
fire axe
weapons
non MR safe gurney
metal medical instruments
tools (e.g. wrench, pliers, hammer, etc.)

The magnet room (1157A) is locked and entry can only be gained by keycard or physical key into the Control Room (room 1157) followed by another physical key or pressing the "Open" button to access the MR Room. Except in cases of extreme urgency, it is advisable to contact one of the emergency contact personnel listed below to escort emergency personnel into the magnet room.

Dr. Wang Zhan, 301-405-3035 or 301-405-2590, wang.zhan@gmail.com, cell 443-858-4213
Christine Rebsch, 301-405-2590, rebsch.c@gmail.com, cell 301-370-4986
Sandy Collier, 301-405-4125, collier@umd.edu, cell 304-671-1176
Dr. Luiz Pessoa, 301-405-2423, pessoa.mri@gmail.com, cell 202-441-2515
Genessey Flint, 301-405-2092, gflint@umd.edu, cell 703-798-6328

If an accident occurs, for instance someone may be pinned against the magnet by a metal object, the following emergency procedures should be used. The worst case would be that additional personnel enter the room to aid the victim of the accident without first screening themselves for metal objects, thus causing further accidents. Assess the level of urgency involving the victim and act based on the following guidelines.

a) If there is no serious injury to the victim, remove the victim from the magnet room.

b) If the victim is pinned by a metal object, enlist the aid of several individuals to help remove the object (all personnel entering the magnet room should be free of metallic objects).

c) If the victim has sustained a life-threatening injury from a metallic projectile and remains pinned to the magnet, then the magnet can be shut down (or "quenched"). Quenching a magnet is a VERY serious response and should ONLY be performed in the case of serious bodily injury to a victim due to projectile ferromagnetic objects. A quench button is located on the wall beside the door to the magnet room and is labeled with a black magnet on a yellow background with a red X through it (see attached picture). Importantly, a quench results in the emission of large amounts of helium, which can cause cryogen burns. The release of helium also quickly displaces the air from the room, resulting in a deadly low oxygen environment if there is no ventilation (if magnet door is closed). The MNC suite is equipped with fire detection equipment, fire pull stations, fire strobes and ceiling-mounted sprinklers.

Appendix G

Imaging Research Facility Internal Operating Procedures

Level 1

Safety Training Course

The MNC SOPs require that all MR personnel update their safety training annually. The MNC Operations Committee subcommittee on Safety and Compliance (referred to as "Safety Committee" in the following text) holds a Safety Training Course at the beginning each academic semester. Other MR personnel can also be designated by the Safety Committee to offer a course to a small group of experimenters.

The Level 1 training course consists of four steps.

- 1) Read the SOPs. This step is required of all personnel who are renewing their training and of new trainees. Reading should be completed before attending the training lecture. SOPs can be found on the MNC Website online course site under resources.
- 2) Watch the Siemens safety video. This step is required only of new trainees. The video will be shown during the first 25 minutes of the training session. Personnel updating their training may arrive at 25 minutes past the start time and skip the video step.
- 3) Attend a safety lecture given by an MNC Safety Committee member or their designee. This step is required of all personnel. The lecture will follow the presentation of the safety video. A question and answer period will follow.
- 4) Attend a tour of the MNC given by an MNC Safety Committee member or their designee in which emergency equipment is pointed out. This step is required of all personnel. The tour will follow the lecture. When these steps are performed for a smaller group, they do not need to follow directly one after the other. However, it is important that the steps be followed in the order shown.
- 5) Complete the MNC MRI Safety Screening Form (Appendix C). An MNC Safety Committee member will then conduct the screening interview process with the trainee in a private room or hallway. Once the interview is complete, the trainee and the interviewer must sign and date the questionnaire. The questionnaire will then be filed in the locked file cabinet in the MNC. The Level 1 MR personnel is responsible for notifying the MR Technologist and/or MR Physicist of any changes to his/her screening form. If any changes need to be made, the Level 1 MR personnel must complete a new Safety Screening Form to be reviewed and signed off on by the MNC Safety Committee.

Level 2

The Level 2 training course consists of two steps:

- 1) Complete Level 1 training and receive Level 1 certification. Level 1 certification must be renewed annually.
- 2) Read the SOPs closely then pass the Level 2 test. The Level 2 test is administered by the MR Physicist.

Appendix G

Operator Training

[Italicized sections are copied and repeated from SOPs]

MRI operator trainees must be certified Level 1 MR personnel. Before certification as an MRI Operator, the trainee must be certified as a Level 2 MR personnel.

Operator training is usually reserved for only a few individuals. The MNC employs Operators during its operating hours. Because these Operators use the technology every day, they are efficient, understand how all of the equipment in the MNC is used, and are vigilant with regard to safety procedures. It is recommended that most users take advantage of the MNC Operators as a resource, allowing the user to focus on running their experiment, increasing the chances of success.

However, because we are a research and teaching facility, we believe that Operator training should be available to MNC users. For instance, new core faculty and research scientists may wish to undergo Operator training. Also, PIs may nominate individuals from their research groups, whom they feel are ready for the responsibilities associated with being an Operator. These individuals are usually nominated for two reasons, 1) because training provides an educational experience, and/or 2) to facilitate collection of research data.

Although the final decision about each individual's qualifications to be a certified Operator is largely subjective, the Safety Committee has generated some objective guidelines for nominating Operator trainees.

- 1) Undergraduates may undergo Operator training as an educational experience only. Undergraduates will only be allowed to advance to the probationary trainee phase, and will not be certified MR Operators or Level 2 Personnel.
- 2) Graduate students may undergo Operator training. The purpose of training graduates is twofold, 1) for the educational experience that it offers, and 2) to allow them to collect data for their dissertation outside the normal operating hours of the facility.
- 3) Non-core faculty, research scientists, post-docs, full-time research assistants, lab technicians, and lab managers may undergo Operator training.
- 4) It is suggested that nomination be restricted to individuals who either have extensive previous experience with MR environments, or that the PI has worked with in a research setting for an extended period, such that the PI is able to reliably gauge the nominee's ability. It is helpful if nominees have interacted with members of the MNC staff prior to nomination.
- 5) Full-time MNC Operators are hired by the MNC Director and the MNC Operations Staff.

Certification of MRI operators must be approved by the MR Physicist. This approval is documented on the form included in Appendix B.

MRI operator trainees undergo intensive personal training with a certified Level 2 MNC Operator. Training progresses through three phases.

Minimum times are purposefully low. Trainees who have extensive previous experience with MRI may only require the minimum times for each phase. For trainees with no previous experience those times may have to be doubled. The training Operator should be a full-time MNC Operator.

Appendix G continued

Observer phase: Trainees observe the training Operator for a minimum of 4 hours of imaging. This phase of training is meant to familiarize the trainee with operating procedures. Trainees move on to the next phase at the discretion of the training Operator.

Trainees should observe all actions of the training Operator. The training Operator should explain their actions as they are performed. This is especially important when putting participants in the MRI device.

2) Assistant phase. The trainee assists the training Operator for a minimum of 10 hours of imaging, with the training Operator taking the lead. This phase of training is meant to give the trainee hands-on experience with the operating procedures, and allow them to gradually begin to perform the duties of a certified Operator. Trainees move on to the next phase at the discretion of the training Operator and the Safety Committee.

Trainees should gain hands-on experience with every action required of an Operator. During this phase, the trainee must become confident with their ability to operate the console, to put participants in the MRI device, and to multitask during the execution of an experimental protocol.

3) Probation phase. Trainees operate the MRI device under the supervision of the training Operator for a minimum of 10 hours of imaging. This phase allows the trainee to build confidence in their ability to perform operating procedures, and develops the level of skill and responsibility necessary to be certified Operators. Trainees perform all operating procedures during imaging, using the training Operator as an information resource only. Trainees may apply for certification from the MR Physicist at the discretion of the training Operator.

Trainees effectively perform all of the tasks expected of an Operator, but with supervision (i.e., the training Operator is in the MNC suite). During this phase, the trainee gains independence; therefore, the training Operator should be sure to allow the trainee to attempt to handle problems on their own. To apply for certification, trainees should show knowledge for all the tasks and actions required of an Operator, show evidence of an ability to put participants and patients at ease during imaging, and show thorough knowledge of the safety procedures. Before certification, trainees must be certified as Level 2 MR personnel, and must show thorough knowledge for the participant safety screening questionnaire protocol.

Imaging Outside Standard Operating Hours

The MNC is a shared facility; therefore, changes to the equipment made by one user affect many users. For this reason, and for reasons of safety, if a user is operating outside of standard operating hours (i.e., outside of the hours when an MNC Operator is available), and there is a problem with the MRI device or any other equipment, the Operator should NOT attempt to fix the problem. Instead, they should report the problem to the MNC staff, so that they may attend to it. If the problem has the potential to damage the equipment, then they should contact the MR Physicist or MR Technologist immediately. Contact information is posted in the MNC manual found in the control room and can also be found in the SOPs (see Appendix B). If a problem occurs with the MRI device or the equipment does not prevent the user from completing their imaging session, the problem should still be reported to the MNC staff. This will allow the staff to effectively track problems with the equipment and keep them working better for all users.

Appendix H

Incidental Anomalous Findings

The approved language to be used in consent forms is below:

The MNC is not a medical facility, does not do clinical work, and an MRI scan at the MNC is not a medical test. It is designed to address research questions and it is not the kind of scan that can be used for any clinical purpose. In fact, if there is an unusual finding in the scan, the MRI technician, or the researcher may not even detect it. However, if the technician or researcher sees something in the scan that appears unusual, the scan could be sent without any personal identifiers to a certified neuroradiologist at the Radiology Department at the University of Maryland Medical School for further review. If the neuroradiologist concurs that this unusual finding should be investigated further by a physician, you will be notified by the principle investigator leading the study.

The PI is responsible for communicating about the general nature of the unusual finding with the MNC Director and Dr. Zhan at MNC. The PI is also responsible for reporting to research participant. Dr. Zhan's contact information is below:

Dr. Wang Zhan, wang.zhan@gmail.com, phone: 301-405-3035 or 301-405-2590

MR Physicist

Maryland Neuroimaging Center