# Standard Operating Procedures

# Maryland Neuroimaging Center (MNC)

University of Maryland | 8077 Greenmead Dr, Bldg 795, College Park, MD 20740

Version 012025

By conducting research at the MNC, you acknowledge that you have read and understand the policies and procedures described herein and will abide by them. Principal Investigators are responsible for their research lab members at the MNC and must ensure their lab members understand MNC policies and procedures and meet all MNC safety training requirements.

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#### INTRODUCTION

The Maryland Neuroimaging Center (MNC) is dedicated to human neuroimaging research at the University of Maryland. The MNC is housed within the Avrum Gudelsky building, conveniently located across the street from the main campus. The center has been designed to foster collaboration among neuroscientists, psychologists, cognitive scientists, engineers, and physicists.

The MNC houses a newly upgraded, research-dedicated Siemens 3 Tesla Magnetom Prisma Fit MRI scanner, ideal for studying human neuroanatomy, as well as neural mechanisms, circuits, signals, and networks. The MNC also hosts a magnetoencephalography (MEG) facility, which offers additional vantage points from which to study the brain.

The MNC began as an initiative of the University of Maryland's interdepartmental Neuroscience and Cognitive Science (NACS) Program. It is available to researchers from the University and to interested researchers from outside universities and institutions. Elucidating the mechanisms of brain development and comparing neurotypical and neurodivergent populations are common areas of focus for researchers who utilize the MNC. Another ongoing area of research involves examining the neural mechanisms underlying expert abilities that serve critical national priorities.

#### **OVERVIEW**

There are inherent hazards and risks in the magnetic resonance (MR) environment, not only for participants but also for the MR Operators, accompanying family members or caretakers, researchers, and others, including housekeeping and building maintenance personnel, and emergency medical responders. MNC researchers must be familiar with this manual and must adhere to and implement its policies and procedures at all times. At a minimum, MNC researchers are expected to be able to keep themselves safe and avoid becoming a hazard to others.

Untrained individuals (e.g., electricians, contractors, visitors, touring groups) must always be accompanied by appropriately trained MR Personnel and should never enter the Control or Scanner Rooms before completing the MNC MR safety screening process. MNC researchers should resist the temptation to show friends or visitors the scanner "up close," as this unnecessarily exposes people to risk. Tours that may bring untrained individuals into the Control or Scanner Rooms must be authorized in advance by MNC staff.

This version of the Maryland Neuroimaging Center (MNC) standard operating procedures (SOPs) has been developed using the 2020 American College of Radiology (ACR) Manual on MR Safety. The ACR manual represents a consensus of the ACR Committee on MR Safety, which comprises professionals representing diverse fields and backgrounds. Many of the MNC's SOPs were copied verbatim from the ACR Manual, but alterations and additions were made to reflect aspects of safety which may be specific to the MNC and the needs of MNC researchers. Some portions of the document were adapted from or taken directly from the MR procedures and

protocols of other large research institutions. These SOPs are intended to be reviewed and updated annually, or more often, if necessary. Questions regarding these SOPs or facility operations can be directed to Sandy Collier, MNC Director of Operations and Finance, or Luiz Pessoa, MNC Director.

#### **CENTER CONTACTS**

Director: Dr. Luiz Pessoa, pessoa@umd.edu, 301-405-2423

Director of Operations and Finance: Sandy Collier, collier@umd.edu, 301-405-4125

MR Physicist: Dr. Wang Zhan, wzhan@umd.edu, 301-405-3035

MR Technologist: Matthew Turner, mturne23@umd.edu, 301-405-4074 MR Technician: Mariah Egerton, megerton@umd.edu, 301-405-8657

Reception: 301-405-2092 Fax: 301-314-0231

MR Control Room (Zone 3): 301-405-2590

Maryland Neuroimaging Center 8077 Greenmead Dr. Bldg 795, College Park, MD 20742

#### SIEMENS AND EMERGENCY CONTACTS

**Life-threatening or other emergencies**: **911** from any phone, 5-3333 from a campus phone, or #3333 from any Verizon Wireless, AT&T, Sprint, or T-Mobile cell phone.

**Non-Emergencies or thefts**: 301-405-3555 (campus phone extension 5-3555). Dial 9 first for calls from campus phones to non-campus lines.

Scanner problems and immediate MR safety concerns: Dr. Wang Zhan: 301-405-3035

You may also be advised to call the Siemens Service Center (1-800-888-7436) for scanner issues. Dial 9 first for calls from campus phones to non-campus lines. Siemens representatives may ask for the following information:

- MNC Prisma Fit scanner functional location: 768268
- MNC Dimplex Chiller functional location: 768269

#### **Additional emergency contacts:**

- Department of Environmental Safety, Sustainability & Risk: 301-405-3960, campus phone extension: 5-3960. Dial 9 first for calls from campus phones to non-campus lines.
- Facilities Maintenance (Work Control): 301-405-2222, or campus phone extension: 5-2222. Dial 9 first for calls from campus phones to non-campus lines.

#### MNC LAYOUT



Figure 1: MNC Layout

# Room numbers with sq. footage:

#### Zone 1: Zone 2: 1100 Restroom 75.71 1151 Kitchen 343.63 1102 MNC Faculty Restroom 75.71 1159 Restroom 1103 Conference Room 210.44 1160 Lab Workspace 269.33 1104 Reception 216.44 1161 Mock Suite Reception 225.05 1161A Changing Room 78.07 1104A Director Office 168.51 1104C MR Physicist Office 104.52 1161B Mock Scanner 190.08 1104D Faculty Office 119.92 1161C Mock Interview Room 81.46 1104E Copy Room 101.59 1161D Mock Waiting Room 126.44 1104F Closet 12.21 1161E Storage Closet 44.27 1104G Closet 11.95 1162 Interview Room 270.83 1164 Collection Room 97.83 1105 Telecom 1107 MNC Engineer Office 153.01 Zone 3: 1108 MEG Lab 816.22 1153 Equipment Room 270.06 1157 Control Room 304 1109 MR Tech 152.01 1111 MR Tech 215.67 Zone 4: 1115 Intake Suite 144.26 1157A Scanner Room *570.59* 1117 Research Group Workspace 305.57

# **SAFETY BASICS**

#### MNC ZONES AND REGULATIONS

The MR facility may be conceptually divided into four zones.



Figure 2: MNC Zone layout.

**Zone 1:** This region includes all areas from the front doors of the MNC and the lobby to the entrance doors of Zone 2. Participants, MR personnel, and MNC staff all access the MR environment by first passing through Zone 1. Participants, visitors, and Non-MR Personnel must be under the direct supervision of Level 1 or Level 2 MR Personnel in Zone 1.

**Zone 2:** This area is the interface between Zone 1 and the more strictly controlled areas of Zones 3 and 4. Participants, visitors, and Non-MR Personnel in Zone 2 must be under the direct supervision (within sight) of Level 1 or Level 2 MR Personnel, except when one of these untrained individuals is in the restroom or locker room. In that case, verbal range is sufficient; however, MR Personnel must be waiting within direct sight of the restroom or locker room door.

Participants, their parents/guardians or caretakers, and any observing Non-MR Personnel should complete and review any forms while in Zone 2, including the safety screening form. All jewelry, **phones, other electronic devices**, purses, bags, backpacks, and other belongings of participants, Non-MR Personnel, etc., should be left in Zone 2. The only exception is shoes, which may be worn in Zone 3. All pre- and post-scan interviews, questionnaires, and testing should also take place in Zone 2.

#### The emergency exit is located at the end of Zone 2 next to the kitchen.

**Zone 3:** This area includes the control room and the equipment room. Unrestricted access by unscreened participants, parents, guardians, caretakers, Non-MR Personnel, or ferromagnetic objects and equipment can result in serious injury or death due to interactions between the individuals or equipment and the immediate MR scanner environment.

Access to Zone 3 by Non-MR Personnel is entirely under the control and supervision of Level 2 MR Personnel. Non-MR Personnel must be accompanied by at least one Level 2 MR Personnel, who is in constant visual contact with the Non-MR Personnel.

To avoid misunderstandings or questions of responsibility, each non-MR Personnel individual entering Zone 3 must be assigned a specifically identified Level 2 MR Personnel individual responsible for them throughout their stay in Zones 3 or 4.

Zone 3 should be physically restricted to Level 2 MR Personnel only. If no Level 2 MR Personnel are present in Zones 3 or 4, the door to Zone 3 must always be shut and locked, regardless of the time of day or the presence of others at the MNC. There should be no exceptions to this guideline.

Labs may not bring electronic devices which are not vital for the actual scan session into Zone 3. One cell phone per lab is permitted in Zone 3.

\*Note: Zone 3 will be referred to as "Control Room" or "Equipment Room" when distinction is needed. Both rooms technically constitute Zone 3.

**Zone 4:** This area is synonymous with the MR Scanner Room. Zone 4, by definition, is always located within Zone 3, as the MR magnet and its cryostat are what constitute Zone 3. **The scanner room door must be kept closed <u>at all times</u>** as a barrier to Zone 4, except when it must remain open for participant setup, cleaning, restocking, or MR system maintenance. The MR Operator can directly observe and control Zone 4 from the operator desk in Zone 3 through the radiofrequency (RF) shielded window. Importantly, controlled access restrictions to Zones 3 and 4 must be maintained during any emergency for the protection of all involved.

#### MR PERSONNEL AND NON-MR PERSONNEL

#### **MNC MR Personnel**:

Those who perform activities or work within the MNC and have successfully completed the MNC's formal MR safety education within the previous 12 months. This training ensures they do not pose a danger to themselves or others in the areas (or Zones) of the MNC to which they have formal access.

Documentation of MR Personnel is maintained by the MNC. This documentation includes the names and expiration dates of all certified MR Personnel at the MNC.

#### **Non-MR Personnel:**

Those who may be professionally affiliated with the MNC but have not successfully undergone the designated formal MR safety education within the previous 12 months. Upon entering the building, Non-MR Personnel must be escorted by a designated, appropriately trained MNC MR Personnel member at all times in all Zones of the MNC.

#### **Untrained individuals:**

Those who are not professionally affiliated with the MNC and have not completed the MNC's formal MR safety education. Untrained individuals include research participants and accompanying parents/guardians or caretakers, as well as visitors, housekeeping personnel, maintenance personnel, emergency personnel, etc. Untrained individuals must be escorted by a designated, appropriately trained MNC MR Personnel member at all times in all Zones of the MNC.

#### **MNC MR Personnel Levels**

There are 2 levels of MNC MR Personnel, as described below.

**Level 1 MR Personnel**: Individuals who have successfully completed the MNC's Level 1 safety training within the past 12 months and have demonstrated competency. Their knowledge base is sufficient to ensure they do not pose a potential threat to themselves or others.

Facility Access: Level 1 MR Personnel are allowed independent access to Zone 1 and Zone 2 of the MNC.

Supervisory Capacity: Level 1 MR Personnel may also escort and supervise Non-MR Personnel and untrained individuals within Zones 1 and 2, provided they are always within eyesight. Level 1 MR Personnel are **not** responsible for the safety of others in Zone 3 or Zone 4.

Level 1 MR Personnel documentation must be signed by both the Level 1 trainee and the individual who oversaw the completion of Level 1 training on behalf of the MNC. This is usually an MNC MR Operator. Documentation is kept on-site at the MNC and logged in an MNC database. Level 1 MR Personnel with a University of Maryland ID card may submit a formal request for door swipe access to Zones 1 and 2 of the MNC.

**Level 2 MR Personnel**: Individuals who have been Level 1 certified in the past 12 months, attended an annual MNC MR emergency drill, and passed the Level 2 test. Thus, they have demonstrated a thorough understanding of MR safety at the MNC, including broader aspects of MR safety issues, MNC MR safety screening procedures, and MNC MR emergency protocols.

Facility Access: Level 2 MR Personnel are given the privilege of independently accessing Zones 3 and 4, in addition to Zones 1 and 2.

Supervisory Capacity: These individuals are responsible for their own safety, as well as the safety of others. They may accompany Non-MR Personnel and untrained individuals in all areas of the MNC. They can also supervise Level 1 MR Personnel in Zones 3 and 4, which Level 1 MR Personnel cannot independently access. Level 2 MR Personnel may also go over the safety screening form with MR study participants and their parent or guardian and perform the metal detector "wanding" on those individuals prior to Zone 3 entry.

Level 2 MR Personnel documentation must be signed by the Level 2 trainee, as well as the certifying MNC representative. It is kept on-site at the MNC and logged in an MNC database. Level 2 MR Personnel with a University of Maryland ID card may submit a formal request for door swipe access to Zone 3 of the MNC. (Zone 4 of the MNC does not have swipe access—it is accessible by those with swipe access to Zone 3.)

**MR Operator**: An individual with current Level 1 and Level 2 MR Personnel certifications who has successfully completed MNC Operator training classes and has proven scanning proficiency and competency on the MNC's Siemens 3T Prisma MRI scanner through hands-on training. MR Operators must log at least 10 scanning hours at the MNC each year to retain their MR Operator status.

Facility Access: MNC MR Operators have access to Zones 1 through 4, which they attained upon certification at Level 2. MR Operators are the only individuals who may operate the MR scanner computer, interact with the controls on the scanner itself, or handle scanner equipment, such as the head coil.

Supervisory Capacity: MR Operators may accompany Non-MR Personnel and untrained individuals in all areas of the MNC, as well as Level 1 MR Personnel in Zones 3 and 4. Additionally, the MR Operator will direct all individuals in the MNC in the event of an emergency.

MR Operator documentation must be signed by the Operator trainee, as well as the MR Technologist and the MR Physicist. It is kept on-site at the MNC and logged in an MNC database.

#### **NEW RESEARCH PROJECTS**

- 1. Email the MR Physicist at wzhan@umd.edu to schedule a meeting about the new project.
- 2. Obtain funding source and IRB approval.
- 3. Complete the online New Research Registration form (mnc.umd.edu/research/research- registration).
  - Monitor your email for your Research ID. This ID must be used when submitting scanning requests to the MNC.
- 4. Sign up for the Level 1 MR Personnel training class and ensure all members of your research lab assisting with the project do the same. This step can be done later in the process, but classes fill up, so it is recommended that you do not wait.
- 5. Meet with the MR Physicist to set up your scan protocol on the Prisma Fit console and discuss any peripheral equipment needed for the scan.
- 6. The MR Physicist will test the agreed-upon protocol with a phantom and notify the PI once the protocol is ready for the scheduling of a pilot scan (i.e., protocol testing with a non-participant human volunteer).
  - For new or modified functional MRI tasks, it is the researcher's responsibility to test the experimental script on the Mock Suite computer until it runs to their satisfaction, and then finally, on the Zone 3 computer before scheduling a pilot scan.
- 7. Complete 1 or 2 pilot scans with volunteers. We suggest recruiting volunteers who have already gone through the MNC Safety Screening process to decrease the likelihood of contraindications.
  - It is strongly recommended that labs analyze data from pilot scans to the greatest extent possible to identify potential issues before participant data collection begins.
- 8. Schedule first participant once pilot scans are complete and your lab has reviewed the quality of the pilot data—NOT before this point.

#### CALENDARS AND ACCESS

All MNC calendars are displayed through Google Calendars and should be accessed via University of Maryland email accounts. When a new lab member arrives or an existing lab member needs access to an additional calendar, the lab should email the MR Technologist(s) and specify to which calendars the lab member will need access. Below are the names of the MNC calendars and brief descriptions of their uses:

The "Events at MNC" calendar will indicate dates or times when an MR Technologist is not available to assist with a scan, and when the MNC is closed due to a holiday. It is also used to display safety trainings and tours.

The "MRI Schedule" calendar will display when a research group has scheduled the Control Room (and thus, the scanner as well), or when the scanner is unavailable due to regular maintenance.

You will notice mandatory 15-minute "buffer" periods before and after each scanning session to allow the MR Operator time to set up for the next scan.

The "Ancillary Rooms" calendar displays reservations which include all rooms within the Mock Suite, including the Mock Scanner Room, Waiting Room, Locker/Changing Room, Interview/Testing Room, and reception desk. Special arrangements must be made ahead of time if a lab would like to enter the Mock Suite when it is already occupied(see Scanner Usage Policies and Scheduling Guidelines below).

The Ancillary Rooms calendar also displays reservations for the Interview Room, Lab Workspace, Intake Suite, Collection Room, and Research Group Workspace.

#### SCANNER USAGE POLICIES AND SCHEDULING GUIDELINES

Scheduling policies are created by MNC staff with input from users. They are reviewed periodically and revised as necessary.

Optimally utilizing and sharing the MR scanner at the MNC is a community effort. MNC users are expected to conduct their research in a courteous manner and be considerate of other researchers regarding scheduling hours and honoring bookings. To avoid unnecessary cancellations and maximize scanner time, researchers are asked to follow these best practices:

- 1) Do not schedule a scan unless the participant has confirmed the appointment date and time.
- 2) The research group should pre-screen the participant using the MNC Safety Screening Form before scheduling to avoid last-minute cancellations due to MR contraindications.
- 3) Confirm the scan time with the participant at least once in the days leading up to the session.
- 4) The participant should be asked to arrive at least 15 minutes before the scheduled scan time.

- 5) Lab research MR Personnel MUST be at the MNC <u>at least</u> 15 minutes PRIOR to the participant's scheduled appointment time (i.e., 30 minutes before the scheduled scanner time), preferably in the reception area to greet them upon their arrival.
- 6) Show consideration when scheduling scans. The MNC MR Technologist cannot scan back-to-back studies throughout the day—they must have time for restroom breaks and lunch.
- 7) Every scan must have a mandatory "buffer" time of 15 minutes before and after each scanning session to allow the MR Operator time to clean the scanner and participant supplies, put away all peripheral equipment from the previous scan, and have the Scanner Room setup back to its original state.
- 8) Rooms and scans may be reserved beginning and ending at 15-minute intervals on or past the hour, for example, the Control Room may be booked from 1:15 pm to 2:00pm, not from 1:10pm to 1:55pm.
- 9) No food or drink can be brought into Zones 3 or 4 by either scan participants or MR Personnel.
- 10) No personal belongings of MR Personnel, Non-MR Personnel, or untrained individuals may be brought into Zones 3 or 4. MR Personnel may only bring into Zone 3 electronic devices which are necessary to facilitate the scan protocol.
- 11) MR Personnel may not bring electronics into Zone 3 for use by untrained individuals (e.g., participants, parents/guardians) or Non-MR Personnel for any reason.
- 12) Include both MNC MR Technologists on cancellation emails. The assigned MR Technologist could change up to the scheduled scan start time.
- 13) Include both MNC MR Technologists and the MNC MR Physicist when a participant discloses a possible contraindication to being scanned. Notify these staff at least 3 days in advance of the scheduled scan to allow sufficient time for thorough research. Sometimes manufacturers of devices, implants, and other products must be contacted directly for MR safety information.
- 14) MNC MR Technologist weekday scanning hours are visible on the "Events at MNC" calendar. Hours begin at 9am, unless otherwise indicated. To maximize MNC MR Technologist availability throughout the day, all requests for weekday morning scans must have an MRI start time of 9am, 10:30am, or 11am. Mornings with no restrictions are indicated on the "Events at MNC" calendar.
- 15) MNC MR Technologist availability on weekends is also visible on the "Events at MNC" calendar. Hours begin at 10am, unless otherwise indicated. All weekend morning scan requests when an MNC MR Technologist is available must have an MRI start time of 10am.

- 17) Schedule your scan time to begin at the time you intend to take charge of the Control Room and schedule your scan end time to be when you plan to leave the Control Room. This means MRI time does not end until the participant is out of the scanner and experimental computers and other equipment are restored to their original states, and the next research group can begin their scan setup. If the scan session time goes past the requested MRI end time, an overage fee will apply. Chronic overages will be monitored by the MNC Director of Operations and Finance.
- 18) If the study is consistently running over into the cleaning time, adjust your schedule request time accordingly.
- 19) Last-minute cancellations result in lost scanning time to all researchers. Records of cancellations, including the reasons when available, will be kept and reviewed by the MNC Director of Operations and Finance. In cases of excessive cancellations or scan time overages which impact other researchers' ability to use scanner time, the MNC may impose scheduling restrictions or conditions upon the research group.
- 20) An MRI scan request cannot be shortened solely to fit within MNC operator hours, or to fit into a time slot, in general.
- 21) Labs with an MR Operator are encouraged to schedule scans during evenings and on weekends, when an MNC MR Technologist is not available.
- 22) Clean up lab materials and remove your personal belongings from any reserved rooms (e.g., Mock Suite, Lab Workspace, Interview Room) by the end of the scheduled time.
- 23) Only reserve the Mock Suite if you need the Mock Scanner, Mock Computer, or the Mock Interview Room's computer. The Interview Room or Conference Room should be used if you do not require those resources. Some labs require multiple areas reserved concurrently or successively. This must be indicated on the Scheduling Form. The Lab Workspace should only be used if all other preparatory rooms are already reserved, since its availability is crucial for labs scanning babies, toddlers, or very young children.

If your lab must use the Mock Suite before or after your scan, but another group has already reserved it before or after your scan, you must ask that lab if they would be willing to overlap for a period on some (or all) rooms within the Mock Suite before you place a request for the Mock Suite and the MRI Scanner. The lab has the right to decline your request at their discretion.

Labs must reserve a preparatory room throughout their reserved MRI time. It needs to be reserved so it is available to store the belongings of both the participant and the lab. That room reservation should continue through the scheduled duration of the MRI and extend 15 minutes past the requested MRI End Time in case the scan runs over.

HOW TO SCHEDULE: contact the MR Techs for detailed instructions. Policies are subject to change.

#### **EMAIL LISTS**

There are two MNC-related email lists which those affiliated with the MNC may request to join:

An **MNC** researcher email list for those who would like to hear about things like scan cancellations, MNC policy updates, technical updates to the scanner, and emergencies at the MNC. Email the MNC MR Technologists to join this email list.

A wider **MNC** community email list for things like the MNC journal club, upcoming neuroscience presentations and events, and job openings. Email Jeremy (jpurcel8@umd.edu) to join this email list.

# MR DATA POLICIES

#### MR DATA DOWNLOAD AND REVIEW

The MR Operator initiates the data transfer process from the scanner to the MNC data storage server immediately after the scanning session is over. The actual transfer is automated and takes place in three-hour intervals at 6am, 9am, noon, 3pm, 6pm, and 9pm. If you do not see your data in the data storage server immediately after the scan, please check again at the next transfer time.

Always check your scan data within 24 hours of your scan to ensure that 1) your data has been received in its entirety; and 2) none of your data was corrupted in the transfer process. It is very easy for the MR Technologists to resend the scan data shortly after the scan, but after 24 hours, it may be impossible to retrieve your data from the scanner.

It is also highly encouraged that research labs visually examine the scan data for quality right away and begin processing the data as soon as possible, so they can immediately relay any problems to the MR Physicist and/or the MR Technologists.

#### MR DATA DE-IDENTIFICATION

Participant names and dates of birth are not entered into the MRI console or recorded in the MRI data (DICOM) header information. In the Patient Name field of the DICOM header, a project-specific participant ID is entered, which usually consists of the experiment's three letter MNC Project ID, followed by three numbers chosen by the lab. In the Date of Birth field of the DICOM header, all participants over two years of age are given a birth date of June 30<sup>th</sup>, followed by their real year of birth for scanner safety calculations.

Note: Structural MRI data (e.g., MPRAGE scans) are generally not considered to be deidentified since high-resolution facial data is retained in the scan. It is considered good practice for research groups to strip structural scans of their face data before sharing it with those outside of their IRB protocol.

#### MR INCIDENTAL FINDINGS (POTENTIAL BRAIN ABNORMALITIES)

It is the responsibility of the Principal Investigator (PI) of each research project to take appropriate action if an incidental finding (i.e., unexpected brain abnormality) is detected in their participant's scans. The MNC has arranged for a certified neuroradiologist at the University of Maryland Medical School in Baltimore to assess incidental findings upon the PI's request and then report back to the PI.

The following procedures should be followed if during a scan the MR Technologist or other researcher identifies an unexpected abnormality in the images:

- 1) The MR Technologist will continue to operate the scan without informing the participant or the participant's parent/guardian or caretaker to avoid alarm. Any other researchers present will also not disclose this finding to the participant or anyone accompanying the participant.
- 2) The MR Technologist will ask the MR Physicist to review the scan.
- 3) The MR Physicist will review the scan and contact the PI.
- 4) At the PI's discretion, the MR Physicist will provide a copy of the scan images to the Medical School.
- 5) The neuroradiologist will review the data and advise the PI of one of the following assessments:
  - a) The incidental finding is non-significant, and no action is needed.
  - b) The incidental finding is non-significant, but the PI should inform the participant (or the participant's parent/guardian or caretaker) that an incidental finding was made.
  - c) The incidental finding *is* significant, and the PI should inform the participant (or the participant's parent/guardian or caretaker) that they should consult a physician for further investigation or assessment.

The following is the approved language to be used in consent forms:

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 principal investigator leading the study.

#### IMPLANT, DEVICE, OR OBJECT DISCOVERED DURING MR EXAM

It is uncommon, but possible that during an MR examination, an unanticipated ferromagnetic implant or foreign body is discovered within a participant. This is typically suspected or detected by means of a sizable image distortion or signal-loss artifact that grows with increasing echo time and is more prominent on gradient-echo relative to spin-echo imaging sequences. In such cases, it is imperative that further image acquisition is put on hold and that the MR Physicist is immediately notified of the suspected findings. The MR Physicist must assess the situation based

on information obtained from the MR Operator and decide what the best course of action might be.

It should be noted that there are numerous potentially acceptable courses that might be recommended, dependent on many factors, including the status of the participant; the location of the suspected ferromagnetic implant or foreign body relative to local anatomic structures; and the mass of the implant or foreign body. Appropriate courses of action could include proceeding with the scan underway or immediately removing the participant from the scanner. Regardless of the course of action selected, it is important to note that the forces on the implant will change and may actually *increase* during the attempt to remove the participant from the scanner bore. Further, the greater the rate of motion of the participant/device through the magnetic field near the scanner bore, the greater the forces acting on that device will likely be. Thus, if at all possible, the device should be immobilized while the participant is being removed from the bore. The scanner bed should be brought out of the bore slowly, cautiously, and deliberately, which will make it more likely that the forces on the device as it moves are weaker and potentially less harmful to the participant. See below for further discussion regarding MR-related forces.

The magnetic fields associated with the MR scanner are 3-dimensional. Thus, especially for superconducting systems, one should avoid the temptation to have the participant sit up as soon as they are physically out of the bore. Doing so may expose the ferrous object to significant torque- and translation-related forces, despite being physically outside of the scanner bore. It is therefore advisable to continue to extract the participant along a straight line course parallel to the center of the magnet, while the participant remains immobile, until they are as far as physically possible from the MR scanner itself and before any other motion vector by the participant or object is permitted.

Should a participant's implanted device be inadvertently exposed to any level of the energies associated with the MR system, the physician responsible for the maintenance of the active device should be contacted before the participant leaves Zone 3. Significant injuries have resulted from such partial exposures, and adequate functionality should be verified and never assumed for critical devices.

#### PROVIDING BRAIN IMAGES TO PARTICIPANTS

The MNC does not print or provide brain images to research participants. Management and distribution of data collected at the center is the responsibility of researchers and governed by their IRB protocol.

#### MR SCANNER SAFETY

#### MR SAFETY CLASSIFICATIONS

Current products marketed with ill-defined terminology such as "nonmagnetic," or outdated classifications such as "MR compatible," should not be presumed to conform to a particular current ASTM International classification.

Similarly, any product marketed as MR Safe but with metallic construction or components should be treated with suspicion. Objects intended for use in Zone 4, including nonclinical incidental products such as stepping stools or ladders, which are not accompanied by manufacturer or third-party MR safety test results under the ASTM International Standard F2503 criteria, should be site-tested as described above.



Figure 4: FDA labeling criteria developed by ASTM International for portable objects taken into Zone 4. The square green MR Safe label is for nonmetallic, nonconducting objects; the triangular yellow label is for objects with MR Conditional labeling; and the round red label is for MR Unsafe objects.

**MR Safe**: A designation indicating that the object or device is safe in all MR environments, without conditions. It is reserved for nonmetallic, nonconducting, and nonmagnetic objects that pose no known hazards in any MR environment.

**MR** Conditional: A designation indicating that the object or device may be safely used in the MR environment, provided the conditions for safe use are met. Decisions based on published

MR Conditional safety claims should recognize that all such claims apply to specifically tested static field and spatial gradient field strengths and only apply to the precise model, make, and identification of the tested object. For example, "MR Conditional having been tested to be safe at 3T at gradient strengths of 400 G/cm or less and normal operating mode."

**MR** Unsafe: A designation indicating that the object or device is known to present safety risks in the MR environment. These are primarily ferromagnetic objects.

#### MR SCREENING OF DEVICES AND OBJECTS

When a participant is in the MR scanner bore, Non-MR Personnel or materials that are not required for the care of that participant should not enter Zone 4.

Participants, visitors, maintenance workers, and others with metallic objects, devices, or tools should be restricted from entering Zone 3 whenever possible.

The MNC keeps a metal detecting wand and a strong handheld magnet (>1000 G) in Zone 3 for screening purposes and equipment testing. The MNC also keeps a smaller, more powerful wand for use in closer proximity to the participant (such as confirming there are no bobby pins in their hair, etc.).

The metal detecting wand enables Level 2 MR Personnel to test for grossly detectable metallic objects on a person or in their clothing prior to Zone 3 entry. It **cannot** detect whether a metallic object is ferromagnetic and it **cannot** be used for the purpose of detecting the presence of metallic implants or onplants, although it could occasionally detect *some* superficial internal devices or implants. It is also not sensitive enough to test whether clothing has been treated with metallic substances.

The handheld magnet is used by MNC Staff to test for grossly detectable ferromagnetic forces from objects that must be introduced into Zones 3 or 4. The handheld magnet is not to be used to detect metallic objects or substances on or within a person's body.

- a. All metallic or partially metallic devices that are on or external to a participant or their caretaker that must be brought into Zone 3 are to be positively identified in writing as MR Unsafe or MR Conditional in the MR environment prior to permitting them into Zone 3. For all device or object screening, verification and positive identification should be in writing.
- b. External devices or objects demonstrated to be ferromagnetic and MR Unsafe in the MR environment may be brought into Zone 3 under specific circumstances if, for example, they are deemed by Level 2 MR Personnel to be necessary and appropriate for participant care. They should only be brought into Zone 3 if they are under the direct supervision of Level 2 MR Personnel who are thoroughly familiar with the device, its function, and the reason supporting its introduction to Zone 3. The safe use of these devices while they are present in Zone 3 will be the responsibility of specifically named Level 2 MR Personnel. These devices must be appropriately physically secured or restricted at all times within Zone 3 to ensure that they do not

inadvertently come too close to the MR scanner and become exposed to static magnetic fields or gradients that might result in their becoming either hazardous projectiles or dysfunctional.

- c. Never assume an MR Conditional or MR Safe status of a device if it is not clearly documented in writing. All unknown external objects or devices being considered for introduction beyond Zone 2 should be tested with the metal detecting wand and the handheld magnet (>1000 G) for ferromagnetic properties prior to permitting them entry to Zone 3. The results of such testing, as well as the date, time, name of the tester, and methodology used for that particular device, should be documented in writing. If a device has not been tested, or if its MR safety status is unknown, it should not be permitted unrestricted access into Zone 3.
- d. All portable metallic or partially metallic objects that are to be brought into Zone 4 must be properly identified and labeled using the current FDA labeling criteria developed by ASTM International in ASTM Standard F2503. Those items that are wholly nonmetallic and not electrically conductive should be identified with a square green MR Safe label. Items that are clearly ferromagnetic should be identified as MR Unsafe and labeled appropriately with the corresponding round red label. Objects with an MR Conditional status should be affixed with a triangular yellow MR Conditional label prior to being brought into Zone 4.
- e. It should be noted that alterations performed by the facility on MR Safe, MR Unsafe, and MR Conditional equipment or devices may alter the MR safety or compatibility properties of the device. For example, tying a ferromagnetic metallic twisting wire or binder onto a sign labeling the device as MR Conditional or MR Safe might result in image artifacts and/or safety issues if introduced into the MR scanner.

As noted above, if MR safety data are not prospectively available for electrically active equipment or objects, they should not be brought into Zone 4 without being subjected to the testing outlined in ASTM International Standard F2503.

If MR safety data are not prospectively available for a given object that is <u>not</u> electrically activated (e.g., wash basins, scrub brushes, step stools), initial testing for the purpose of this labeling is to be accomplished by MNC Staff who are Level 2 MR Personnel by using the metal detecting wand and the handheld magnet (>1000 G). If grossly detectable ferromagnetic properties are observed using the handheld magnet, it is to be labeled with a circular red MR Unsafe label. If none are observed, a triangular yellow MR Conditional label is to be attached to the object. It is **only** when the composition of an object and its components are known to be nonmetallic and not electrically conductive that the green MR Safe label is to be affixed to a device or object.

#### STATIC MAGNETIC FIELD-RELATED ISSUES

To determine whether a given implant or device in a participant has been tested and considered safe, MR Conditional labeling of implants and devices provides two numbers:

- 1) the maximum static magnetic field (B0); and
- 2) the maximum static magnetic field gradient (dB/dx).

For implants that are *even* <u>weakly</u> <u>ferromagnetic</u>, magnetic translational and rotational forces on the implant might move or dislodge the device from its implanted position.

For all implants that have been demonstrated to be nonferrous, the risk of implant motion is primarily limited to those resulting from Lenz forces alone.

#### **Spatial Field Gradient**:

The spatial field gradient (SFG; sometimes called the static field gradient) characterizes the variance in the temporally fixed static magnetic field surrounding the MR scanner. The SFG is the rate of change in the magnetic field as a function of position around the MR system. The SFG typically decreases with increasing distance from the physical poles of the magnet hardware of a typical cylindrical, horizontal-field magnet. The SFG decreases with increasing distance from the physical ends of the magnetic poles. For a typical cylindrical, horizontal-field magnet, the location of the magnet poles, and thus maximal SFG would correspond to a loop at the end of the magnet, corresponding to the outer edges of the openings or entrance(s) to the magnet bore.

#### Lenz forces:

Faraday's Law states that a changing magnetic field will induce a voltage and subsequent current in a perpendicularly oriented electrical conductor. Lenz's Law extends this, asserting that the induced current will generate a secondary magnetic field that opposes the original magnetic field, effectively working against the motion. The faster the participant is moved through the scanner's static field, the greater the voltages, current, and secondary magnetic field within a susceptible implant will be. This can result in a participant feeling a tugging or pulling of the implant within their body. **Note that this will occur even if the conductor is metallic but nonferromagnetic.** 

#### TIME-VARYING GRADIENT MAGNETIC FIELD-RELATED ISSUES

#### **Induced Voltages:**

Participants with implanted or retained wires in anatomically or functionally sensitive areas (e.g., myocardium or epicardium, implanted electrodes in the brain) should be considered at higher risk, especially from faster MRI sequences, which require rapid time-varying gradient magnetic fields, such as echo planar imaging. Echo planar imaging may be used in such sequences as diffusion-weighted imaging, functional imaging, and perfusion-weighted imaging. This risk may depend on whether the wire is directly exposed to the time-varying gradient magnetic fields of the MR scan to be performed, *or* may be part of an anticipated induced current pathway

#### TIME-VARYING RADIOFREQUENCY (RF) MAGNETIC FIELD-RELATED ISSUES

To avoid potential issues and injuries associated with RF fields, all unnecessary or unused electrically conductive materials external to the participant should be removed from the MR system before the onset of imaging. It is insufficient to merely disconnect and leave unused, unnecessary electrically conductive devices, such as surface coils or EMG leads, in the MR scanner with the participant during imaging. All electrical connections, such as those used for surface coils or participant interfaces of monitoring systems, must be visually checked by the MR Operator prior to each use to ensure the integrity of the thermal or electrical insulation.

#### **Thermal Considerations**

**Specific absorption rate** (**SAR**): The MNC's MRI scanner software calculates the SAR, a whole body-averaged estimate of the rate of absorption of RF energy by the participant expressed in units of watts per kilogram. SAR does not provide the total dose of energy absorbed by a participant, nor does it tell us about the rate of absorption of any particular region of the body.

**Specific energy dose (SED)**: SED is the total energy absorbed by the participant, reported in units of joules per kilogram, or kilojoules per kilogram. At this time, the MNC's MRI scanner software cannot calculate SED.

The primary rationale for implementing SAR or SED limits is to protect a participant from experiencing core temperature elevations, physiologic stress, or discomfort related to inordinately high thermal loads from high-SAR pulse sequences or long scanning sessions.

It should be noted that the thermal load associated with an MR examination is a separate phenomenon from focal RF-related thermal injury (i.e., burns). Although discomfort related to high thermal load during MR may be experienced by the participant, an actual burn does not occur if that load is sufficiently dissipated over time and space. Additionally, limiting the SAR or SED of an MRI examination does not necessarily reduce the risks of a thermal injury—burns have occurred in participants even when MR systems were operating within guidelines for RF power deposition. Thus, separate precautions for burn prevention are implemented. MNC MR Operators are trained to set participants up in the scanner in such a way to reduce the likelihood of RF burns. This includes ensuring a 5mm distance between the RF head coil and the participant's body, positioning a participant in such a way to prevent conductive loops (more on this next), and informing the participant about the importance of not forming conductive loops. MNC MR Operators are also trained to regularly ask participants about their comfort level between scan acquisitions.

Various health conditions may impair an individual's ability to manage a thermal challenge during MRI, including fever and obesity. Medications, including diuretics, beta-blockers, calcium blockers, amphetamines, and sedatives, can alter the participant's thermoregulatory responses to a heat load. Importantly, certain medications may have a synergistic effect with RF radiation with respect to tissue heating.

**Focal heating**: Electrical voltages and currents can be induced within electrically conductive materials (e.g., skin or cables) that are within the bore of the MR scanner during MRI acquisition. This can result in heating and burning of human tissue, especially when the conductive materials form conductive loops. The larger the diameter of conductive loops, the greater the potentially induced voltages and currents, and thus the greater the potential for resultant thermal injury to adjacent or contiguous participant tissue.

**Transmitting coil proximity/contact**. The participant's skin should not touch any part of the head coil, as thermal injuries or burns can occur from this contact. Pads meeting Siemen's specifications must be wedged between the participant and the head coil at any point of contact as a safeguard. A single-layer bedsheet is insufficient insulation or spacing.

Large caliber–induced current loops. It is important to recognize that large conducting loops may be created by any points of skin-to-skin contact, (e.g., thigh-to-thigh, finger-to-finger, or hand-to-hand). Thigh-to-thigh contact is a commonly formed large caliber—induced current loop which has been reported to cause inner thigh burns. Similarly, finger-to-thigh contact has reportedly resulted in burns to the fingers or outer thighs. The greater the caliber of an induced current loop, the greater the amount of current and potential for heating within that loop. Thus, the ACR recommends providing pads in such areas to prevent excessive heating and burns caused by large caliber—induced current loops.

The concern for induced current loops is even greater when electrically conductive wires or leads are involved. When electrically conductive material (e.g., wires, leads, implants) are required to be entirely or partially within the volume undergoing direct RF irradiation during MRI, care should be taken to ensure that no large caliber electrically conducting loops (including participant tissue) are formed within the MR scanner during imaging. The FDA has noted several reports of serious injury, including coma and permanent neurological impairment, in participants with implanted neurological stimulators who underwent MRI examinations. The injuries in these instances resulted from heating of the electrode tips.

Resonant heating. Furthermore, it is possible, with the appropriate configuration, lead length, static magnetic field strength, and other settings, to introduce resonant circuitry between the transmitted RF power and the lead. This could result in very rapid and clinically significant lead heating, especially at the lead tips, in a matter of seconds with a magnitude sufficient to result in tissue thermal injury or burns. This can also theoretically occur with implanted leads or wires even when they are only a few centimeters long or they are not connected to any other device at either end. It has been demonstrated in vitro that heating of certain implants or wires may be clinically insignificant at 1.5T but quite significant at 3T. However, it has also been shown that specific implants might demonstrate no significant thermal issues or heating at 3T but may heat to clinically significant or very significant levels in seconds at 1.5T. Thus, it is important to follow established product MR Conditional labeling and safety guidelines carefully and precisely, only applying them to the static magnetic field strengths at which they had

been tested. MR scanning at either stronger or weaker magnetic field strengths than those tested may result in significant heating where none had been observed at the previously tested field strength.

Participants with long electrically conductive leads, such as Swan-Ganz thermodilution cardiac output—capable catheters or Foley catheters with electrically conductive leads, as well as electrically active implants such as pacemakers, ICDs, neurostimulators, and cochlear implants and any associated leads, cannot be scanned at the MNC, even if only part of the lead pathway is within the volume to undergo RF irradiation.

When any portion of electrically conductive materials external to the participant are required to be within the volume of the transmitting RF coil during imaging, care should be taken to place thermal insulation between the participant and the electrically conductive material, while simultaneously attempting to keep the electrical conductor from directly contacting the participant during imaging. It is also appropriate to try to position the leads or wires as far as possible from the inner walls of the MR scanner if the body coil is being used for RF transmission. If it were necessary that electrically conductive leads directly contact the participant during imaging, application of cold compresses or ice packs to the contact areas should be considered.

#### **Special considerations for RF thermal issues:**

*Unconscious or sleeping participant*. Consideration should be given for the unconscious or sleeping participant to have all attached leads covered with a cold compress or ice pack at the lead attachment site for the duration of the MR study.

Electrically conductive clothing. Some materials used in clothing have been increasingly associated with thermal injury or burns in participants undergoing MRI. Recent trends in the manufacturing of clothing and other related products have incorporated metallic and conductive materials (e.g., antimicrobial silver and copper) that are not reliably disclosed in labeling. Such clothing products include but are not limited to sportswear (including underwear, bras, and socks), orthotic-related items (e.g., stump covers or stump shrinkers), and blankets. Reliance on clothing labeling is not sufficient, as the Federal Trade Commission guidelines allow clothing to contain impurities at levels as high as 5%, which could be significant for a participant undergoing an MRI examination. Especially for anatomic regions within or near the volume undergoing direct RF (B1) field irradiation, it is important that such clothing not be worn into the scanner. The MNC has a limited supply of MR Safe scrubs, so it is highly recommended that lab personnel take all opportunities to advise participants of clothing appropriate for the scanner before the day of the scheduled scan.

Skin staples or multiple implants in proximity to each other. Although thermal risks associated with individual small dermal implants and piercings are generally low, dermal implants that are in proximity or directly contact one another may increase the risk of thermal injury, especially if the items are close to the volume associated with RF energy

power deposition. An example of this might include skin staples and superficial metallic sutures (SMSs). Participants with skin staples or SMSs might be permitted to undergo the MR examination if the skin staples or SMSs are not ferromagnetic and are not within or near the anatomic volume undergoing direct RF power deposition.

**Participants with tattoos**. It should be noted that there is no standardized method of assessing tattoos which can assure one of the safety of any given tattoo. Consequently, **all participants with tattoos should be advised of the risk of burns and told to notify the MR Operator if they experience any discomfort in the area of a tattoo site. If discomfort occurs, scanning must be stopped immediately and cautiously resumed** *only* **if a new corrective measure (e.g., application of an ice pack, cold compress, or wet towel) has been taken. If a cold compress has already failed to prevent discomfort, the scan must be discontinued.** 

Participants with tattoos which are near or within the head coil (i.e., head, neck, upper shoulders) **must** have cold compresses or ice packs placed on the tattooed areas to be kept in place throughout the MR process, especially if the study includes fast/turbo spinecho or other high-RF-duty-cycle MR sequences. The potential for RF heating of the tattooed tissue increases if the tattoos are extensive, dark, loop-shaped, or in the area of the eye (e.g., tattooed eyeliner). If a participant with a tattoo near or within the head coil cannot or will not tolerate a cold compress or ice pack for the duration of the scan, the scan will not proceed.

Automatically exclusionary tattoos. Participants with facial (including tattooed permanent makeup/microblading), scalp, or genital tattoos will not be scanned at the MNC. Tattoos less than 48 hours old at the time of the scan have the potential for smearing or smudging around the edges, so participants may not be scanned during this time period. Participants with tattoos not acquired in a licensed tattoo studio (e.g., jail, prison, home) or outside of the United States may not be scanned at the MNC.

Please do not email a photo (or a description) of a participant's tattoo to the MNC MR Physicist or MR Operators to inquire about compliance with MNC protocol. Any ambiguities (e.g., "Does this tattoo extend onto the participant's face?") should automatically err on the side of the more restrictive, safer policy.

Participants with magnetic tattoos. Metallic tattoos are a relatively new type of temporary tattoo and are NOT MR safe, as they pose a significant risk of burns. Such tattoos are always exclusionary for MR scanning. As the name implies, these have a metallic appearance and are typically applied whole to the skin surface like a stamp or decal rather than being injected under the skin like standard tattoo ink. Note that metallic tattoos are sometimes used to enhance standard tattoos, so the fact that placement of a given tattoo involved standard tattooing procedures does not necessarily imply that there is not also a metallic tattoo component. Standard tattoos never have a metallic appearance, so any tattoo having a reflective metallic appearance is always exclusionary.

*Drug-delivery patches and pads*. Some drug-delivery patches contain metallic components. Scanning the region of the metallic foil may result in thermal injury or alteration in drug-delivery rate by heating. Removal or repositioning of a prescribed patch can result in alteration of the dose, so the participant must consult their prescribing physician before taking such action.

## MR SCREENING PROCESS

All Non-MR Personnel and participants, as well as those accompanying them (untrained individuals), who intend to enter Zone 3 must first go through the MNC MR safety screening process. The MNC Safety Screening Form can be found in Appendix 2. Labs may use additional screening items for their own use, but the MNC Safety Screening Form will be the only form of record at the MNC and must be completed in its original format and in its entirety.

The screening process for untrained individuals, Non-MR Personnel, and MR Personnel should <u>essentially be identical</u>. It should be assumed that all who enter Zone 3 may enter Zone 4 and the bore of the MR system at any time and be exposed to the static or time-varying magnetic fields.

For example, a pediatric participant on the scanner table being sent into the bore may cry or yell for their parent in Zone 3, who may instinctively rush to their child in Zone 4 and lean into the bore of the scanner.

Any parent/guardian or caretaker accompanying the participant into Zone 3 must go through the same safety screening process as the participant. They must remove and lock away all jewelry, electronics, and other belongings in Zone 2, complete and review the MNC MR Safety Screening Form with Level 2 MR Personnel, and go through the metal detector wanding process by Level 2 MR Personnel prior to entering Zone 3. No electronics or other items can be brought into Zone 3 by research MR Personnel to be given to untrained individuals or Non-MR Personnel for any reason.

Untrained individuals and Non-MR Personnel who plan to accompany the participant into Zone 4 must pass their safety screening to the extent that they are safe to be scanned, themselves, as they may be exposed to the same forces of the participant in the vicinity of the bore. Untrained individuals and Non-MR Personnel with any possible foreign bodies or implants which have not been documented by a physician and cleared before the day of the scan will not be allowed entry into Zone 4 for any reason.

As discussed in detail later, the metal detecting wand is not sensitive enough to be used for the purpose of detecting implants or foreign bodies inside of a person, although it is possible for the wand to detect an especially large metallic body which is close to the skin's surface.

#### MR SCREENING STEPS

There are three steps of formal MR safety screening at the MNC:

1) The MNC MR Safety Screening Form is first completed in its entirety in Zone 1 or Zone 2 by the participant, as well as anyone accompanying the participant who may enter Zone 3, regardless of whether the accompanying individual plans to enter Zone 4.

No empty responses are accepted; each question must be answered with a *yes* or *no*—otherwise additional detailed information must be acquired. All *yes* or *maybe* answers require the attention and approval of the MR Operator (usually the MR Technologist) or the MR Physicist (more on this below).

If the participant is a minor, their parent/guardian may help the participant complete the form (more on this below). If an adult participant is believed to be an unreliable historian or is otherwise unable to complete the form (e.g., due to cognitive or physical limitations), their caretaker or Level 2 MR Personnel may help the participant complete the form.

2) Level 2 MR Personnel must interactively review the completed MNC MR Safety Screening Form in its entirety with the participant (see below for pediatric and clinical population participant screening instructions). Level 2 MR Personnel should also ensure at this time that all regulations under the section "Physical Screening and Participant Changing/Gowning Rooms (p. 61)" are being adhered to prior to proceeding to the Zone 3 entrance. This includes an assessment of clothing safety. The MR Operator will make the final assessment of clothing at the Zone 3 entrance.

Any question answered in the affirmative on the MNC MR Safety Screening Form will require a written explanation of the circumstance by the participant or their parent/guardian or caretaker. The acting MR Operator or the MR Physicist should be alerted to review such answers before the participant is brought to the Zone 3 entrance. If upon review, the MR Operator is concerned for the participant's safety in the MR environment, or if additional information is needed, the scan cannot proceed as scheduled. If a participant is uncertain about a possible contraindication, the Level 2 MR Personnel should also alert the MR Operator before the participant is brought to the Zone 3 entrance.

If, ultimately, the Level 2 MR Personnel believes the participant is safe to proceed with the MR scan, but the MR Operator disagrees, the Level 2 MR Personnel must always defer to the MR Operator. See the section "MR Screening Risk Assessment" for additional contraindication documentation requirements.

# **Pediatric participants**

Pediatric participants (i.e., participants under age 18) should be considered unreliable historians and must be interviewed <u>with</u> their parent/guardian by Level 2 MR Personnel in Zone 1 or Zone 2. Pediatric participants aged 10 or older must also be interviewed a *second* time, without their parent/guardian present. This is done to ensure the participant is not withholding information from their parent/guardian which may be pertinent to MR

safety. Following review, the pediatric participant's form must be signed and dated by the parent/guardian and the Level 2 MR Personnel who reviewed the form with them.

#### Parents/guardians

Next, the Level 2 MR Personnel must review the MR Screening Form of the parent/guardian who will be accompanying the participant into Zone 3. The review with the parent/guardian should be done as thoroughly as if the parent/guardian were to be scanned themselves, even if they have no plans to enter Zone 4.

# Minors who are not the participant may not enter Zones 3 or 4.

# Adult participants accompanied by a caretaker

If a caretaker has completed the adult participant's MNC MR Safety Screening Form, Level 2 MR Personnel should review the form with both the caretaker and the participant. All three should sign and date the form.

#### Caretakers of adult participants

If an adult participant's caretaker will accompany them into Zone 3, their Screening Form must be carefully reviewed and signed and dated, as well. The caretaker must also remove all jewelry, belts, etc., and lock all their personal items away as if they were a participant. Otherwise, the caretaker may not enter Zone 3, and they must be supervised by lab MR Personnel in Zones 1 or 2 for the duration of the scan. They may not wait outside of the building, in their car, in the lobby, or leave and come back for the participant.

Pillows, stuffed animals, personal blankets, and other comfort items brought from outside of the MNC represent potential risks and should never enter Zones 3 or 4. Anyone under the age of 18 accompanying a participant to the MNC must be under the direct supervision of additional lab MR Personnel in Zone 1 or Zone 2 throughout the entirety of the MR scan. They may not wait outside, in a car, in the lobby, or leave and come back.

All completed MNC MR Safety Screening Forms (and any supplemental safety documentation) are kept in a secured location at the MNC.

3) Before leaving Zone 2, Level 2 MR Personnel must have adult participants, parents/guardians, and caretakers ensure all pockets are empty by having them turn all of their pockets inside-out. The pockets of pediatric participants must be physically checked by Level 2 MR Personnel—it is not sufficient to have the pediatric participant check their own pockets or turn their pockets out, nor is it sufficient for the parent/guardian to check the pediatric participant's pockets.

Glasses may not be worn into Zone 3 by Non-MR Personnel unless it puts the person at risk of harm. MR Safe prescription eye goggles are available for use in the Scanner Room in half-step increments from -6 to +4. Research MR Personnel should come to the MNC on the day

of the scan with the participant's prescription in writing, so the MR Operator can prepare the goggles before the participant arrives, if time allows. Plain contact lenses are strongly encouraged, though, as the MR head coil cannot always accommodate the goggles due to space restrictions. Unfortunately, it is impossible for the MR Operator to predict whether a given participant will fit into the head coil with the goggles.

The following items, whether they contain metal or not, must be removed from the body or clothing while in Zone 2. They cannot be brought through the Zone 3 entrance:

Participant, parent/guardian, caretaker, MR Personnel, Non-MR Personnel		Additionally, for the participant
Cell phones	Contact lenses with sensors, circle lenses, big eye lenses, or contacts with color-changing effects	Hair products (also no wet hair)
Tablets	Belts	Eyeshadow
E-books	Keys and keychains	Eyeliner
Electronic watches	Key FOBs	Eyebrow liner, gel, filler
Biomonitoring devices	Wallets	False eyelashes
Traditional watches	Coins	Mascara
Laptops	Belts	Lipstick
Pagers	Cards with magnetic strips	Blush and other powders
All body piercings (metal, glass, plastic, etc.)	Batteries	Concealer and foundation
Decorative implants	Nail clippers	Lotions and sunscreens
Earrings (all materials)	Nail files	Magnetic nail polish
Necklaces (all materials)	Safety pins	Weaves
Bracelets (all materials)	Paper clips	Braids (with synthetic or other hair)
Rings (all materials)	Money clips	Hair extensions
Any other jewelry (all materials)	Pocket knives	Athletic or yoga clothing
Bobby pins	Dentures	Antimicrobial clothing
Barrettes (all materials)	Partial plates	Anti-odor clothing
Hair ties and scrunchies (all materials)	False teeth	Moisture-wicking clothing
Beads (all materials)	Hearing aids	Anti-wrinkle clothing
Wigs	Eyeglasses	Anti-static clothing

Toupees	Artificial limbs	
Hair pieces		
Magnetic false		Compression socks,
eyelashes		pants, sleeves, etc.
Hair attached with		
metallic threading,		
clips, clasps, beads, etc.		

Figure 5: Items not to be brought into Zone 3.

Once the MR Operator is ready for the participant, those who have followed all above safety screening steps may be led to Zone 3 by research MR Personnel. The participant will be asked by the research MR Personnel or MR Operator to remove their shoes. A metal detecting wand is then used by the MR Operator or research Level 2 MR Personnel as a final check for metal outside of their body. The parent/guardian or caretaker will also undergo the metal detection procedure and may be asked to remove their shoes temporarily during the metal detecting, to avoid a false positive.

*Metal detector wanding procedure*. The perimeter of the body is wanded while the participant stands in a starfish-like stance (i.e., arms out to the side and legs somewhat spread, without stretching so far as to cause discomfort or affect balance). Then, the participant will be told to transition to a plank stance (i.e., feet together and arms resting at their side) so the Level 2 MR Personnel or MR Operator can wand the participant from front to back, beginning at the participant's toes, moving up the body, over the face and hair, and proceeding down the back, ending at the participant's heels.

Throughout the wanding process, the metal detecting wand should be run as close to the body as possible, without touching the participant. If a participant is wearing loose clothing, it may be necessary to move the clothing closer to the body with the wand. Particularly close attention should be paid to the hair and shoulder area, including the shoulder blades. Bra straps and other clothing items which set off the wand near the top of the shoulders or the neck area should be removed in the restroom or locker room. Alternatively, bra straps with metal strap adjustment parts may simply be tucked under the participant's arms, as long as the metal is not resting in the armpit or between folds of skin during the scan. If a participant may be more comfortable in scrubs or a gown after removing their bra or other clothing item, they should be offered whatever is available.

It is imperative that any participant who leaves Zone 3 after having been wanded—even if only momentarily—goes through the pocket checking and wanding process again before entering Zone 3.

# RESEARCH MR PERSONNEL AND MNC MR PERSONNEL SCREENING

All MR Personnel and MNC MR Staff are to undergo the MR screening process as part of their Level 1 MR Personnel training to ensure their safety in the MR environment. MR Personnel must report any change in their medical history to the MNC MR Technologists or MR Physicist

as soon as possible. This includes any physical trauma experienced or medical procedure undergone since their previously reviewed MNC Safety Screening Form.

#### MR RISK ASSESSMENT

The MNC MR Technologist or MNC MR Physicist will <u>always</u> have the final say when it comes to determining a person's safety in the MNC MR environment.

Documentation of all contraindications on the MNC Safety Screening Form **must** be provided to both the MNC MR Technologists and the MR Physicist **prior** to the day of the scan, preferably *at least* 3 days prior to the scheduled MR scan to allow time to request and receive further information from physicians or manufacturers, for example.

Contraindications which require documentation include, but are not limited to:

- implanted or onplanted devices
- orbital traumas
- metallic foreign body penetrants
- intracranial aneurism clips

Documentation of these items/situations is required, even if the potential participant reports that no metal or metallic materials have been removed or are otherwise no longer present. Please see the sections below for general documentation requirements for each situation.

The following are always **unacceptable** forms of documentation:

- phone confirmation by the practitioner
- verbal histories by the participant
- signed documentation or verbal histories provided by a nonphysician

It is strongly recommended that research labs email redacted versions of all documentation to the MNC Technologists and the MNC MR Physicist for review. All personally identifiable information of potential participants **must** be removed before being sent to the MNC. All documentation must also be brought by the lab on the day of the scan in <u>physical form</u>, to be included with the participant's formal MNC MR Safety Screening Form. Documents cannot be printed at the MNC.

Once the MNC Technologists and MR Physicist receive documentation which identifies the type of implant or foreign object within the participant, best-effort assessments are made to identify the conditions for MR safety of the implant or object. Efforts include searching for formal testing by the manufacturer, product labeling of the implant or object, and/or peer-reviewed MR safety testing of the specific make, model, and type of implant or object. MR safety review is only of value if testing was performed on an implant or object of *precisely* the same make, model, and type; and the object or device has not been altered since implantation. Furthermore, devices which are not FDA-approved under MNC scanning conditions cannot be scanned.

It is essential to note that a participant with an implant or foreign body may have safely completed other MR scans at the same static magnetic field strength or even the same MR scanner, but this is insufficient evidence of the participant's safety and should not be relied upon to determine whether a participant will be safely scanned at the MNC. Variations in static magnetic field strength, static magnetic field gradient, orientation of the implant or foreign body relative to the static magnetic field or its static magnetic field gradient, and rate of motion through that static magnetic field gradient, as well as other factors, are variables that are impossible to control or reproduce. These variables may not have resulted in an adverse event in one circumstance but may result in significant **injury or death** on a subsequent MR exposure.

For example, at another facility, a participant with a foreign body in his eye entered an MR scanner and underwent the entire MR examination without issue but went blind as he was brought out of the scanner due to interactions between the metallic foreign body in his retina and the static magnetic field of the MR system.

#### **Implanted or onplanted devices:**

A participant with an implant may have safely undergone a prior MR examination at any given static magnetic field strength. This fact is insufficient evidence of the implant's safety and should not be relied on to determine the MR safety status of that implant for future MR examinations.

Documentation of an implanted or onplanted device must include the manufacturer, model, and type, with the serial number. The name of the surgeon and hospital where the device was placed must be provided, as well as the date of surgery and the dates of any follow-up surgeries or any alterations of the device. Patient cards provided by the manufacturer of the device are helpful, but not sufficient without all other aforementioned details, and also accompanied by written and signed clearance from the surgeon who placed the device or the physician who monitors the device. Electronic copies are acceptable *if* the surgeon's or physician's signature is on the document, or the signature is on a separate letterhead which specifically references the required documentation.

Remember that providing all documentation and being cleared by a surgeon or physician does not mean a participant is safe to be scanned at the MNC—the MR Technologists and MR Physicist must confirm that this specific device meets all safety parameters for the scanner and scan protocol.

All untrained individuals and Non-MR Personnel with an implant or onplant device (especially implanted medication pumps, cochlear implants, or other electromechanically activated devices) on which they are dependent should be precluded from entering Zone 4 and prevented from passing the 5-G line unless the device is specifically cleared in writing for scanning at the MNC by the surgeon or licensed physician who ordered the implant. The MNC Physicist must also review the documentation and clear this participant in writing, with a signature.

#### History of ferromagnetic foreign body penetration:

Prior to being permitted entry into Zone 3, all participants and Non-MR Personnel with an unknown foreign body or a history of injury associated with a ferromagnetic foreign body must undergo further investigation. Examples of acceptable methods of screening include obtaining

participant history (particularly in the form of written documentation), plain x-ray films, prior CT, or recent MR studies of the anatomic area in question. The MNC will **not** scan participants who may have been injured by a penetrant which is ultimately of unknown or uncertain composition, as it may contain a metallic component, and therefore cannot be assumed to be MR safe. They must be cleared by a radiologist's review/assessment of prior plain x-rays, CT, or MR images obtained since the suspected traumatic event.

Non-removable piercings and decorative implants fall into this category and require written documentation, which must include the type of object, manufacturer, and specific model, all of which are necessary for the MNC MR Technologists and the MR Physicist to attempt safety verification. The MNC will **not** scan participants with such a non-removable piercing or implant without this information. Verbal assurances that the implant or piercing is titanium, glass, plastic, etc., is not sufficient. **This policy includes research staff who will remain in the scanner room during scanning.** 

#### History of orbital trauma:

All participants with a history of orbital trauma by a potential ferromagnetic foreign body are to have their orbits cleared by a radiologist's review/assessment of prior plain x-rays, CT, or MR images obtained since the suspected traumatic event. This clearance must be in writing and signed by a radiologist who has reviewed the images. All metal workers should also obtain the same, as they are at an increased likelihood of having metal fragments, even if they always wore eye protection and do not believe metal has ever entered their eyes.

#### Intracranial aneurysm clips:

A participant with an aneurysm clip may have safely undergone a prior MR examination at any given static magnetic field strength. This is insufficient evidence of the aneurysm clip's safety and should not be relied upon to determine the MR safety status of that aneurysm clip for future MR examinations.

Documentation of the clip must include the manufacturer, model, and type, with the serial number. The name of the surgeon and hospital where the device was placed must be provided, as well as the date of surgery and the dates of any follow-up surgeries or any alterations of the device. Patient cards provided by the manufacturer of the device are helpful, but not sufficient without all other aforementioned details, and also accompanied by written and signed clearance from the surgeon who placed the device or the physician who monitors the device. Electronic copies are acceptable *if* the surgeon's or physician's signature is on the document, or the signature is on a separate letterhead which specifically references the required documentation.

The MNC MR Physicist should confirm the participant is safe to be scanned with the clip by either confirming in an email (which must be printed and brought by the lab on the day of the scan) or signing off on the official safety screening form, verifying the safety of the clip before the MR Technologist or another MR Operator should move forward with the scan.

#### Pacemakers/ICDs:

Not allowed in Zone 4.

#### POPULATIONS REQUIRING ADDITIONAL CONSIDERATION

#### **Pregnant participants:**

According to ACR guidelines, the safety of MRI at field strengths higher than 1.5T (i.e., 3T, 7T) during pregnancy has not been thoroughly assessed. Theoretical concerns include time-varying gradient and RF magnetic fields, potential acoustically related safety issues, and heat deposition in tissue, respectively. As a result, pregnant participants will not undergo MR imaging at the MNC.

#### **Pregnant MR Personnel:**

MR Personnel are permitted to work in and around the 3T MR environment throughout all stages of their pregnancy. Acceptable activities include, but are not limited to, positioning participants, scanning, and entering the MR system room in response to an emergency. Although permitted to work in and around the MR environment, pregnant MR Personnel are requested not to remain within the MR scanner bore or in Zone 4 during scanning. These recommendations are based on the ACR guidelines.

## Participants on parole:

Situations wherein participants on parole are wearing metallic restraining devices, such as RF identification or tracking bracelets, could lead to adverse events including 1) ferromagnetic attractive effects leading to participant injury, 2) ferromagnetic attractive effects leading to device/battery pack damage, 3) RF interference with the MRI study and secondary image artifact, 4) RF interference with the functionality of the device, and 5) RF power deposition leading to heating of the bracelet, tagging device, or its circuitry. Therefore, any participant wearing an RF bracelet, metallic handcuffs, or an ankle cuff will not undergo imaging at the MNC.

#### Participants who exceed 250kg or cannot fit safely into the bore or head coil:

The 3T Prisma scanner table is designed to support weight up to 250 kilograms, so participants weighing more than that cannot be scanned at the MNC. Although a participant may not exceed the weight limit of the table, they may not be able to fit comfortably or safely into the scanner bore. Any area of the participant's body which may rest against the sides of the scanner must have pads meeting Siemen's specifications between that body part and the scanner wall—it is not sufficient to use a sheet or a towel, for example. Additionally, Siemens requires a minimum of a 5mm distance between the participant's skin and any part of the head coil. Any area where the 5mm gap cannot be maintained must have pads meeting Siemen's specifications wedged between the skin and the head coil to prevent thermal injuries or burns. Additionally, a minimum distance of 5mm must be maintained between the participant's body and the wall of the scanner bore to avoid burns or peripheral nerve stimulation. A towel or a single-layer bedsheet is insufficient insulation or spacing.

#### MR APPROPRIATE CLOTHING

It is imperative that any individual undergoing an MR procedure must **remove** <u>all</u> metallic personal belongings and devices on or in them, <u>whether the item is ferromagnetic or not</u>. This

includes removing removal of ear piercings, body piercings, jewelry, cosmetics possibly containing metallic particles (such as eye makeup or magnetic eyelashes), fitness-tracking or other electronic watches, traditional watches, cell phones, pagers, contraceptive diaphragms, metallic drug-delivery patches, and clothing which may contain metallic fasteners, hooks, zippers, or other loose metallic components and clothing items that may have been treated with metallic substances.

It has become common for brand-name athletic and athleisure clothing to treat their clothing with metallic solutions or incorporate metallic threads. These materials put the MR participant at risk of thermal burns, even if the clothing is not near the head coil. Anyone who might enter Zones 3 or 4 should be instructed to wear 100% cotton or wool fabrics, as those items are less likely to be treated with metallic substances, but please note that clothing companies can and do bind metals to cotton, wool, polyester, yarn, nylon, acrylic, and other types of fibers. Companies are not required to pass this information on to regulating bodies, retailers, or the consumer, unless the clothing article's metallic impurities reach a threshold of 5% of the overall product.

Lab members who screen or schedule participants for their study are urged to stress to participants, as well as any caretaker who may accompany the participant into Zone 3 or beyond, that they **should not** come to the MNC wearing athletic, athleisure, training, yoga, or workout clothing. This includes, but is not limited to athletic bras, underwear, boxers, undershirts, socks, shirts, shorts, pants, sweats, hoodies, and yoga pants. Please note that metal detecting wands and handheld magnets have been shown ineffective at identifying metallic threads or substances in clothing items which have burned participants in the MR scanner. MR Operators may ask a participant if they are wearing athletic clothing under their outer layer of clothing, but will not check any participant's undergarments to verify the participant's statements.

Participants may **not** wear into the scanner any clothing advertised as moisture-wicking, antistatic, anti-odor, antimicrobial, antibacterial, anti-wrinkle, UV-protective, compression, thermal, insulating, or cooling. Athletic clothing with a metallic sheen should also be treated with suspicion and is not allowed. Additionally, clothing containing fabric marketed with a specific brand-name (e.g., Nano-Tex "intelligent fabrics", Zircon Linen, Healthguard finishing) cannot be worn into the scanner. For participants who wish to cover their head and do not have an appropriate covering, the MNC can provide MR-safe coverings. Similarly, there are MR-safe hair clips and piercing jewelry "retainers" available.

#### FULL STOP/FINAL CHECK

A "full stop and final check" performed by the MR Operator is recommended to confirm the satisfactory completion of MR safety screening for the participant, their parent/guardian, or caretaker; lab members; and all MRI and peripheral equipment immediately prior to crossing from Zone 3 to Zone 4. The purpose of this final check is to confirm that all screening has been appropriately performed and to ensure that there has been no change status while in Zone 3.

# SCANNING REQUIREMENTS

# MR PERSONNEL REQUIREMENTS FOR SCANNING SESSIONS

## **Adult, Non-Clinical Participants**

#### **Before and After the Scanning Session:**

An MR Operator *and* a minimum of one other MR Personnel member of any Level must be present in Zones 3 or 4 when an adult, non-clinical participant is in Zone 4 (the scanner room), regardless of whether scans are actively being acquired. During this time, the two MR Personnel will always be within range of communication of one another. The MR Personnel member may not exit to Zones 2 or 1 for any reason while the MR Operator is setting the participant up in the scanner.

Additionally, before or after scanning, while the participant is in Zone 4, either the MR Operator or other Level 2 MR Personnel must be in Zone 4 with the participant at all times. This rule is not in effect once the MR Operator is ready to begin the scan and closes the Zone 4 door.

#### **During the Scanning Session:**

While the scanner is actively acquiring scans, both an MR Operator *and* at least one additional MR Personnel member of any Level **must** be present. Neither may exit to Zones 2 or 1 for any reason, unless the participant is removed from the MR scanner and leaves Zone 4.

The MR Operator will be in Zone 3 during scan acquisitions, and usually the other MR Personnel member will also stay in Zone 3 during adult, non-clinical scans; however, the other MR Personnel member is allowed to be in Zone 4 at this time, even if that MR Personnel member is only certified at Level 1.

#### **Pediatric or Clinical Participants**

#### **Before and After the Scanning Session:**

Whenever a pediatric participant or clinical participant is in Zone 4, there must be an MR Operator *and* a minimum of **two** other MR Personnel members of any Level in Zones 3 or 4, regardless of whether scans are actively being acquired. None of these MR Personnel may exit to Zones 2 or 1 while the participant is in Zone 4. During this time, all three MR Personnel will always be within range of communication. Additionally, either the MR Operator or another Level 2 MR Personnel must be in Zone 4 with the participant at all times, until the scan is about to begin and the door to Zone 4 must be shut.

#### **During the Scanning Session:**

While the scanner is actively acquiring scans of a pediatric participant or clinical participant, an MR Operator *and* a minimum of two other MR Personnel members of any Level **must** be present in Zones 3 or 4. None of these MR Personnel may exit to Zones 2 or 1 for any reason, until the participant is removed from the scanner and Zone 4.

The MR Operator will be in Zone 3 during all scan acquisitions. During pediatric or clinical participant scans, usually one lab MR Personnel member will stay in Zone 3 and another lab MR Personnel member will stay close to the scanner in Zone 4, either to observe the participant or bring comfort to them. The MR Personnel member who stays in Zone 4 with the participant during scanning may be certified at Level 1 or Level 2.

#### OTHER REQUIREMENTS FOR SCANNING SESSIONS

#### **Auditory Considerations:**

The MNC requires **everyone** within Zone 4 during scan acquisition to wear adequate hearing protection, whether they will be in the scanner bore or elsewhere in the Scanner Room. According to the Prisma documentation, if you are using the Siemens headphones, you MUST also provide the participant with earplugs for additional hearing protection (The FDA requires hearing protection of 30 dB or greater and the Siemens headphones alone only provide protection of 13 dB).

The MR Operator will either physically assist the participant in properly placing their hearing protection, or provide verbal and/or visual instruction. Before leaving Zone 4 to begin scanning, the MR Operator should visually verify the proper placement of hearing protection of all who will stay in Zone 4 during scan acquisition. Anyone without hearing protection properly in place may not be scanned, nor may they be elsewhere in the scanner room during scan acquisition.

#### **Squeeze bulb:**

The scanners are equipped with a squeeze bulb that allows the participant to set off an audible and visual alarm through the intercom in Zone 3 in the event of an emergency (See Squeeze Bulb Response Protocol in the Emergency Protocols section). The squeeze bulb should ALWAYS be made available to participants, unless some alternative method of constant monitoring is employed (e.g., MR Personnel accompany the participant in the Scanner Room during scan acquisitions and closely monitor the participant). The MR Operator should ensure the squeeze bulb is properly connected to the red port at the foot of the MR table before each participant's scanning session.

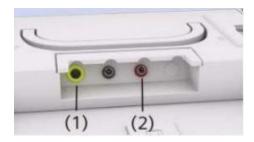


Figure 6: The squeeze bulb should be securely connected to the rightmost port.

#### Physiological Data Collection and Audio Delivery:

The MNC is equipped with leads and devices manufactured by BioPac that can be used during MR scan acquisition for the collection of data including pulse, respiration, galvanic skin-response (GSR), and electromyography (EMG). The pulse ring and respiration belt may also be used for the acquisition of gated scans. Also available is an EyeLink eyetracking system, which collects measurements like eye movement and position. Sensimetric S14 earphones in the Scanner Room offer the delivery of stimuli through high-quality audio, while simultaneously attenuating scanner noise (labs must provide their own earphone foam tips). Labs may also provide their own equipment if it is cleared by the MR Physicist.

Please note that only specially designed electrodes can be safely used within the Scanner Room and must be used in strict accordance with the manufacturer's guidelines. Level 2 MR Personnel and lab MR Operators must request lead and cable training from the MR Technologists before they may independently use the physiological collection devices in the MR environment.

#### MR OPERATOR TRAINING

A Principal Investigator (PI) who conducts research at the MNC may nominate a candidate from their lab to pursue MNC MR Operator training. MR Operator trainees must be certified as Level 2 MR Personnel before beginning training to be an Operator. Labs which would like to scan outside of MNC MR Operator availability (e.g., evenings, weekends) are especially encouraged to nominate an MR Operator before the next MR Operator training class begins.

MR Operator certification is not guaranteed. Demonstration of skills and responsibility is required before the MNC MR Operator and MR Physicist can certify a trainee. Once certified, MR Operators agree to comply with these standard operating procedures and report in a timely manner any safety-related adverse events to MNC staff. Operator training will involve the following steps:

- 1) Training Phase: Two- hour virtual lecture followed by two-hour safety instruction and scanning demonstration in Zone 3 by the MR Physicist.
- 2) Observation Phase: Close observation of a minimum of two scans and booting/shutdown procedures. This step can take place when trainee becomes certified at Level 2.
- 3) Assistant Phase: Progressively increasing hands-on training. Training consists of 6 scans or 6 hours of scan time, whichever comes first. Trainee can receive earlier certification if they meet all criteria to progress to next phase.
- 4) Probation Phase: Progressively more independent hands-on training. Training consists of 6 scans or 6 hours of scan time, whichever comes first. The trainee can be certified once they pass the checklist exam.

NOTE: In exceptional circumstances, the PI may request that the trainee receive an additional two scans/two hours of Probation Phase training. After such request, the trainee will either be certified or denied certification. Conversely, not all trainees may require the maximum training times as determined by the MNC Physicist and MR Operator.

Renewal of MR Operator status is contingent upon continued demonstration of safe operation of the MR scanner and maintenance of best practices in the MR environment, as described in these standard operating procedures. Participation in yearly emergency drills and a minimum of 10 hours of MR scanner operation within the previous 12 months are also required to maintain active MR Operator status at the MNC.

#### EMERGENCY PROTOCOLS

#### Safety Responsibility and Authority

The impulse to respond immediately to emergencies must be tempered by an orderly and efficient process to minimize risks to the victim and others. The acting MR Operator (usually an MR Technologist) has the authority and responsibility to direct all present. The MR Operator will decide the best course of action, whether that be activating the emergency power off button or initiating a quench. The MR Operator also may decide to end a study at any time, evacuate participants from Zones 3 and 4, or take other actions they deem necessary.

All Level 1 and 2 MR Personnel should follow the direction of the MR Operator, even if their commands violate general SOP protocol, such as Zone restrictions. If the MR Operator is incapacitated, all will take direction from the most senior Level 2 MR Personnel present. While the MR Operator has safety oversight, it is imperative that researchers still voice any safety concerns they may have to the MR Operator. For example, researchers should immediately point out safety procedures they think the MR Operator may have missed or forgotten. Safety at the MNC requires vigilance on behalf of all levels of MR Personnel.

Additionally, the acting MR Operator also has the responsibility to protect the MR scanner and system from damage. The MR scanner and system components may be extraordinarily sensitive to changes in environment, including vibration, power supply, and water damage. Due to the local climate, the facility may have to contend with earthquakes, tornadoes, fires, ice storms, snowstorms, brownouts, or blackouts.

#### Summary:

- The MR Operator (usually the MR Technologist) is responsible for the screening and safety oversight of individuals at the MNC.
- In an emergency, other researchers, participants, and visitors should follow all instructions of the MR Operator, even if those instructions contradict general MNC protocol.

#### **Information to provide to Emergency Call Center and Emergency Responders**

- 1) Identify the location of the MNC: 8077 Greenmead Dr, Bldg 795, College Park, MD 20740. Provide the Control Room/Zone 3 phone number 301-405-2590, as cell phone reception is not reliable in the MNC. Remember: when making calls from campus phones to non-campus lines, you must first dial 9.
- 2) Provide details of the emergency and be sure to inform the emergency call center that the MRI magnet is deadly and always on.

- 3) If possible, have a second researcher provide directions and meet the emergency responders at the door of the alleyway on the left side of the building.
- 4) When emergency responders arrive, assume they know nothing about the MR magnet, even if you told the emergency call center over the phone. Inform them of the deadly risk of projectiles around the magnet. Tell them the magnet is always on, and even if the magnet has been quenched, it may still have a significant magnetic field, so you MUST go through the safety screening process with them.
- 5) Ensure that they understand that no metal may be brought into the magnet room.
- 6) Screen ALL emergency responders for metal in the body as you would anyone else who enters the Scanner Room.
- 7) Guard the Scanner Room from any additional emergency personnel who arrive. Keep track mentally of the location of the responders, if possible.

#### **General Squeeze Bulb Response Protocol**

- 1) Stop the current scan acquisition by clicking the "Stop Icon" button on the scanner console using the mouse. (Do NOT hit the Table Stop button unless the participant is injured by the table.)
- 2) Stop the audible alarm by pressing the alarm bell button at the bottom center of the intercom (See intercom diagram item 4)
- 3) While holding down on the intercom talk button (See intercom diagram item 1), ask the participant if something is wrong. Be sure to activate the participant's speaker (See intercom diagram 2) and let go of the talk button, so you can hear the participant's response.
- 4) If necessary, enter the room to further investigate and/or correct the problem. Correcting the problem may involve anything ranging from giving the participant a blanket, to removing the participant from the scanner bore.



Figure 7: Siemens Prisma Fit intercom: 1) The Zone 3 speak mode button (must be held in continuously to speak to the participant and released to hear the participant). 2) The listen button (will pick up both the participant's voice and the scanner noise). Press once to hear continuously and press again to end. 3) The Table Stop button. 4) The squeeze bulb alarm button (push once to end the alarm).

#### Table Movement Injury (i.e., Table Stop) Protocol

1) If a participant is injured by table movement, immediately press one of the scanner's Table Stop buttons (see Figure 8). This will cut power to the table, causing it to stop, as well as stop the scan. Alternatively, you can simply mash the center button on the scanner movement panel to stop the table where it is and attempt to help the participant without disabling the table electronically.



Figure 8: At top and bottom left, the Scanner Room Table Stop buttons. At right, the Control Room/Zone 3 Table Stop button. Note: to reset, press button at the back of the intercom console.

2) After pressing the Table Stop button DO NOT attempt to pull the bed out or you will damage the table motor. You MUST decouple the scanner table from its motor by pulling out the dark blue brake lever under the right side of the scanner table, OR you may undo the table stop by holding the scanner panel participant in and out table buttons for about one second.



Figure 9: Table Stop brake.

3) Only after pulling out the blue brake may you manually pull the table out of the scanner bore by the lip of the table with your body weight. (Do NOT pull the immobile rail at the foot of the table gantry.)



Figure 10: Pull the table out by the lip. Do not grab the bar at the foot of the table.

- 4) Do NOT allow the participant to sit up or move from the raised scanner table until the MR Safe ladder is in place beside the table, OR you have re-engaged the table motor and turned off the table stop process and can bring the scanner table to the floor.
- 5) If a medical emergency or serious injury has resulted from table movement, follow the general medical emergency protocol.
  - To reset the table:
    - 1) Move the bed manually until it is about one inch from the end of the gantry
    - 2) Push the dark blue brake lever back into the table.
    - 3) If you stopped the table initially by hitting one of the red Table Stop buttons on the side of the scanner table, push the red button in and slightly turn the button while pushing it in, until it pops out. <u>Do this as soon as possible.</u>
    - 4) Move the bed completely to the end of the gantry
    - 5) Turn off the table stop process by holding the scanner panel in and out buttons for about one second.

#### **Emergency Power Off (EPO) Protocol**

The Emergency Power Off button stops electrical power to all parts of the MR scanner. It does not in any way affect the magnetic field of the scanner! It does not turn off the lights in any of the rooms, nor does it turn off any of the computers, including the reconstruction or Siemens scanner computers which are housed in the Equipment Room. Remember: the scanner button boxes and any leads or cables will still have power, so be aware that electrical or fire hazards may still be present.

If the EPO button is engaged and a participant is in the scanner bore, decouple the scanner table from its motor by pulling out the lever under the right side of the scanner table. Then pull the table out of the scanner bore by lip of the table. Do NOT pull the immobile rail at the foot of the table. The participant must not be allowed to get down from the table until the MR Safe ladder is in place.

- The EPO button is used if:
  - 1) Water or coolant is near scanner equipment which could be electrified.

- E.g., flooding in the vicinity of the Control, Scanner, or Equipment Rooms, coolant is leaking from the scanner, the sprinkler system is activated
- 2) There is a fire in the MNC (see **Fire** protocol)
- 3) There is a fire *risk* in the Control, Scanner, or Equipment Rooms due to an electrical short or equipment failure.
- 4) There is some other catastrophic equipment failure, or there are loud noises are emanating from the magnet room

#### Three EPO Buttons:

- 1. In the Control Room, to the left of the doorway to the Scanner Room, below the oxygen monitor.
- 2. In the Scanner Room to the immediate left of the doorway, as one enters from the Control Room. The Scanner Room and Control Room EPO buttons are roughly positioned adjacent to one other on the dividing wall of the two rooms.
- 3. In the Equipment Room, to the left, as one enters from the hallway.

NOTE: reset button as soon as possible by turning to the right until it pops back into place

#### **Ouench**

For most MRI systems, a quench causes the scanner to lose its magnetic field by explosively boiling off cryogens from inside of the scanner. At the MNC, the scanner is filled with liquid helium. The system is designed to direct the helium out of the building through a duct. In as little as 20 seconds after the scanner begins to quench, the magnet can cease to be superconductive.

Although the helium which boils off in gaseous form from the scanner is lighter than air and will float to the top of the room, the sheer amount of helium can quickly and fully displace the air from the scanner room. This can cause loss of consciousness within 10 seconds, followed by asphyxia and even death. If the helium makes contact with a person's skin, the extremely low temperature of the helium (-452°F) can cause severe burns. Therefore, in the event of a quench, everyone should be evacuated immediately from the scanner room—preferably before the quenching begins.

#### A quench may be:

- 1) Spontaneous
  - (e.g., helium leaks from the scanner, the scanner quenches itself in self-preservation, vibrations from a seismic event cause a quench)
- 2) Planned
  - (e.g., the scanner is decommissioned and conditions are safe)
- 3) Initiated in an emergency

In the event of an unplanned, emergency quench, it is imperative that all people be evacuated as quickly and safely as possible from Zone 4. A manual quench of the MR magnet in an emergency is begun when the MR Operator pushes the quench button in Zone 3 or the quench button in Zone 4 (See Figure 11 below). One quench button is located on a round console above the researcher's computer. The other one is in the scanner room on the adjacent wall next to the window.

In practice, the entire process of a quench takes 1 to 3 minutes once the button has been pushed. Once the helium release from the scanner begins, the magnetic field should disappear in about 20 seconds. However, considerable residual magnetism may remain, and all emergency personnel must be restricted from entering Zones 3 or 4 with their equipment until the MR Operator or MR Physicist verifies that the magnetic field has completely dissipated. MNC access, in general, should be immediately restricted until the MR Physicist or personnel from Siemens arrive. This is especially true if cryogenic gases are observed to have vented partially or completely into Zone 4, as evidenced in part by the sudden appearance of white clouds or fog around or above the scanner.



Figure 11: At left, the Control Room quench button in red, with yellow sticker and plastic shielding. At right, the Scanner Room quench button in yellow.

The *only* person to decide to initiate a quench is the acting MR Operator, and that is only after careful consideration and preparation because of the risks to persons, equipment, and the facility. Unless the MR Operator is incapacitated, no other MR Personnel (besides the MR Physicist) should take the initiative to quench the magnet. Before choosing to quench the magnet, the MR Operator should contact both Siemens and the MR Physicist, if feasible. In the event of a life-threatening emergency, it is also advisable to consult the emergency call center or emergency responders to determine the best course of action.

The magnet should *not* be quenched if no one is injured or trapped in Zone 4, and there is no fire situation (**See Fire Protocol**). Any object or device on or inside the scanner—<u>no matter how small</u>—should *not* be attempted to be removed; this may alter or destroy the Siemens engineer's precise calibration of the magnet. Furthermore, the force of the magnetic field may pull heavier or denser objects back, possibly damaging the scanner or injuring those attempting to remove the object. Therefore, the object should be left where it is, and the MR Physicist and Siemens must be contacted immediately. To safely remove the object, they may choose to conduct a controlled static magnetic field ramp-down, which does not require a quench.

#### Summary:

Quench the scanner ONLY if:

- A person is trapped against magnet AND experiencing a life-threatening emergency
  - o E.g., blood loss, respiratory restriction, cardiac arrest
- A person in Zone 4 is experiencing some other emergency for which movement could cause further injury (e.g., neck or spinal) and emergency personnel must enter with MR Unsafe tools or supplies

#### Do NOT quench the scanner if:

- A projectile is pinned to the magnet, but no one is trapped by it
- There is an emergency around or within the scanner, but the participant is not trapped and can be removed safely
  - o E.g., seizure, respiratory or cardiac arrest
- The scanner initiates a quench on its own
  - Evacuate Zones 3 and 4, close the doors, and call the MR Physicist and Siemens
- Helium leaks from the scanner
  - Evacuate Zones 3 and 4, close the doors, and call the MR Physicist and Siemens

If an item of any size is stuck to the magnet, even a coin or a paperclip, do NOT remove it and do NOT quench the magnet. Call the MR Physicist and Siemens.

#### **Quench Protocol**

- 1) Remain calm and assess the situation.
- 2) End the scan, if applicable. Assuming the participant is the victim, reassure them over the intercom that you will be coming to their assistance and instruct them to remain in place.
  - o If the participant is not the victim, it is likely that the participant is not within the scanner bore. If the uninjured participant is in Zone 4 at the time the injury to someone else occurs, direct the research MR Personnel to escort the participant to Zone 3 and ask them to ensure the participant does not go back into Zone 4. However, if the victim *is* the only other MR Personnel present (besides the MR Operator), then direct the participant to call emergency services from the Zone 3 phone.
- 3) Immediately go to the injured participant in Zone 4 and begin assessment as the first step of first aid.
  - Do NOT attempt to remove an impaling object from a person, especially if they are trapped within or against the magnet—more blood loss may occur.
  - Do NOT attempt to remove or dislodge a person from the scanner who is trapped by the impaling object.
  - If the participant or other victim is neither trapped nor impaled, remove them from Zones 3 and 4 BEFORE beginning any first aid or life-saving aid, such as CPR.
  - If the participant is immobile, unsteady, or unconscious, transfer them from the scanner table to the MR Safe gurney with the help of the research MR Personnel and evacuate the participant and all others from Zones 3 and 4.

- If the power is out, decouple the scanner table from its motor by pulling out the brake lever under the right side of the scanner table. Then pull the table out of the scanner bore by lip of the table. Do NOT pull the immobile rail at the foot of the table (See Table Stop Protocol).
- 4) Delegate tasks (e.g., placing emergency calls or meeting emergency personnel outside of the building) to whichever research MR Personnel are available.
- 5) If there is fire or smoke, instruct the research MR Personnel to evacuate the participant and any other people to a safe location, away from the building and follow the fire procedure.
- 6) Consult Siemens, the MR Physicist, and/or emergency personnel before deciding to quench the scanner, if possible.
- 7) Evacuate everyone from Zones 3 and 4 and then close the door to Zone 4 BEFORE initiating the quench. If unable to evacuate the victim from Zone 4, open the scanner door BEFORE initiating a quench. (Anyone inside Zone 4 while the door is closed could quickly suffocate. Additionally, cryogenic gases released into Zone 4 could cause severe burns.)
- 8) If all are evacuated from Zones 3 and 4, ensure both doors are closed. This will decrease the chance of emergency workers entering the MR environment
- 9) Press the quench button from Zone 3, if possible. If life-saving aid must be administered, the MR Operator may delegate this task to the research MR Personnel in the Lab Workspace (See Cardiac or Respiratory Arrest Protocol).
- 10) If additional research MR Personnel are available and Zones 3 and 4 could not be evacuated, the MR Personnel should guard those areas from emergency personnel and other untrained individuals until the MR Operator has confirmed the magnetic field has completely dissipated.
- 11) Only once the MR Operator, MR Physicist, or Siemens personnel are able to confirm that the magnetic field is completely down, should emergency personnel be allowed to enter Zones 3 and 4. Until this is confirmed, emergency personnel who must enter Zones 3 and 4 must go through the entire MR safety screening process.
- 12) If the MR Physicist or Siemens have not been contacted, notify them. In the event the MR Physicist cannot be reached, call the MR Technologists.

CRITICAL NOTE: reset button as soon as possible (2-3 minutes) by turning to the right until it pops back into place. Failing to do so will warm the magnet too much, resulting in prolonged down time for the scanner.

#### **Cardiac or Respiratory Arrest Protocol**

- 1) Remain calm.
- 2) End the scan and reassure the participant over the intercom that you will be coming to their assistance. Instruct them to remain in place.
- 3) Direct research MR Personnel to call emergency services.
- 4) Immediately go to the victim and begin assessment as the first step of first aid.
- 5) Remove the participant from scanner bore using the scanner controls.
- 6) Direct research MR Personnel to bring the MR Safe gurney to the table and have them help you move the participant onto it. Do not allow the participant to move from the table on their own. Emergency personnel must never be allowed to bring their own stretcher or gurney into Zones 3 or 4.

- 7) Escort the participant on the gurney out of Zones 3 and 4, to the Lab Workspace. Have the research MR Personnel ensure the doors to Zones 3 and 4 are closed behind you to decrease the chance of emergency workers ending up in the vicinity of the MR environment when they arrive.
- 8) If you know CPR, begin chest compressions in the Lab Workspace. Stay with the participant until help arrives.
- 9) Direct research MR Personnel to retrieve the AED from its location between the Mock Suite and the Zone 2 restroom.
- 10) If the participant is experiencing (or begins experiencing) cardiac arrest, open the AED case and follow the step-by-step audio instructions.
- 11) Direct research MR Personnel to meet emergency personnel, brief them, and escort them to the victim.
- 12) Provide any assistance necessary to emergency personnel.
- 13) The MR Physicist, MR Technologists, or MNC Director of Operations and Finance should be contacted if they have not already been notified.

Never attempt resuscitation or medical treatment within the Scanner Room (Zone 4). This puts all present at risk of injury from ferromagnetic objects carried by emergency personnel when they arrive. Therefore, the victim should be immediately moved out of Zone 4, and Zone 3, if possible, to the Lab Workspace, the designated location to begin CPR or other life-saving techniques until emergency response personnel arrive.

A quench should be considered in any situation in which a victim in critical condition cannot be removed from Zone 4 and emergency personnel may be forced to enter (see **Quench Protocol**). For example, a victim is trapped against the scanner and is experiencing a life-threatening emergency, or movement of the victim from Zone 4 could cause further injury, such as when a victim may have experienced a neck or spinal injury. Any situation in which emergency personnel may be forced to enter Zone 4 requires a quench to be seriously considered, even if they are MR safety screened before entry.

As stated previously, the MNC has an AED in Zone 2. It is in a case on the wall, between the Mock Suite and the Zone 2 restroom. It is vital to remember that the AED at the MNC is **not** MR Safe and cannot be brought into Zone 4. It should not be used in Zone 3, either, if avoidable.



Figure 12: The AED is in the Zone 2 hallway, mounted on the wall between the Mock Suite and the restroom.

#### Summary:

- Never attempt resuscitation or medical treatment within the Scanner Room (Zone 4). Do not attempt it within the Zone 3 if it can be avoided.
- Maintain access restrictions to Zones 3 and 4 during resuscitation or other emergency situations.

#### Non-life-threatening Participant Medical Emergency Protocol

- 1) Remain calm.
- 2) End the scan and reassure the participant over the intercom that you will be coming to their assistance. Instruct them to remain in place.
- 3) Direct research MR Personnel to call emergency services.
- 4) Immediately go to the victim and begin assessment as the first step of first aid.
- 5) Remove the participant from scanner bore using the scanner controls.
  - If the participant is unconscious, unsteady, or immobile, direct research MR Personnel to bring the MR Safe gurney to the table and have them help you move the participant onto it. Do not allow the participant to move from the table on their own. Remember, emergency personnel must never be allowed to bring their own stretcher or gurney into Zones 3 or 4.
  - In the event of power failure, decouple the scanner table from its motor by pulling out the brake lever under the right side of the scanner table. Then pull the table out of the scanner bore by lip of the table. Do NOT pull the immobile rail at the foot of the table (See **Table Stop Protocol**). Do NOT allow the participant to move from the table before the MR Safe ladder is in place.
- 6) Escort the participant out of Zones 3 and 4 and into the Lab Workspace. Have the research MR Personnel ensure the doors to Zones 3 and 4 are closed behind you to decrease the chance of emergency workers ending up in the vicinity of the MR environment when they arrive.
- 7) Administer appropriate aid if you have been trained to do so. Stay with the participant until help arrives.
- 8) Direct research MR Personnel to meet emergency personnel, brief them, and escort them to the victim.
- 9) Provide any assistance necessary to emergency personnel.
- 10) The MR Physicist, MR Technologists, or MNC Director of Operations and Finance should be contacted if they have not already been notified.

#### RF Burn Injury (During a Scan) Protocol

- 1) Remain calm.
- 2) End the scan and reassure the participant over the intercom that you will be coming to their assistance. Instruct them to remain in place.
- 3) Direct research MR Personnel to call in the emergency.
- 4) Immediately go to the victim.
- 5) Remove the participant from scanner bore using the scanner controls.
- 6) Help the participant get off of the scanner table and out of Zone 4 safely.

7) Apply burn treatment packets from the first aid supply box on the desk behind the Zone 3 door. If packets are not available, apply a damp, cold towel to the burn until EMS arrives.

#### **Panicked Participant Protocol**

- 1) Remain calm.
- 2) End the scan and check in with the participant over the intercom.
- 3) Reassure the participant over the intercom that you will be coming to their assistance. Instruct them to remain in place.
- 4) Help the participant into Zone 3.
- 5) Remain calm, speak softly, and reassure the participant that everything is all right and that their reaction is understandable and is not uncommon.
- 6) If the participant calms down and wants to proceed with the scan, you may do so if feasible and if the situation allows.
- 7) Be empathetic. If the participant is very upset, do not pressure them to get back into the scanner.
- 8) Once the participant is ready to leave the Zone 3, the research MR Personnel should help the participant put their shoes on and escort them out of the room.

#### **Threatening or Dangerous Participant Protocol**

- 1) If the MR Operator is the person directly interacting with the participant, the research MR Personnel should call emergency services and request immediate assistance.
- 2) Put some distance between yourself and the participant. Do not make intense eye contact.
- 3) Speak softly to the participant and refrain from having a judgmental attitude. Try to remain neutral, although it may be difficult with an irrational participant. Try to demonstrate control of the situation without becoming demanding or authoritative. Seek to smooth the situation over rather than bully the patient into behaving appropriately.
- 4) Evacuate the MNC, if necessary. Dial 911 immediately after leaving the building.

#### Fire, Smoke, or Explosion Protocol

- 1) Remain Calm.
- 2) Direct the research MR Personnel to activate the fire alarm in the Zone 2 hallway.
- 3) Hit the nearest EPO button if the fire is in the vicinity of the Scanner Room before removing the participant from the scanner bore. This is to avoid electrocution (See EPO Protocol).
- 4) Retrieve the participant from the scanner bore and direct the research MR Personnel to evacuate everyone from Zones 3 and 4 and to call 911 once they are out of the building. Research MR Personnel should remember to alert the call center of the danger of the scanner magnet.
  - o If the fire is not close to the Scanner Room, you may remove the participant using the table movement buttons.

- 5) If the fire is not in the Scanner Room and is small, use the nearest fire extinguisher to attempt to put it out. If the fire is not small or it is unsafe to attempt to put it out, evacuate the building.
- 6) If the fire *is* in the Scanner Room, MR Personnel may only attempt to put the fire out with the MR Safe fire extinguisher IF the fire is small and the conditions are safe to do so. If the fire in the Scanner Room is large or cannot be put out using only the MR Safe fire extinguisher, and there is no one trapped inside of the scanner, do not continue to try to stop the fire. Evacuate the building and call 911.
  - The pin in the MR Safe fire extinguisher in Zone 3 is strongly ferromagnetic and is MR Unsafe. The pin MUST be removed in Zone 3 BEFORE the fire extinguisher can be used in the MR environment.
- 7) Call 911 if research MR Personnel have not already and warn the call center of the danger of the scanner magnet.
- 8) Remain in sight of the building, but in a safe area to wait for the arrival of firefighters.
- 9) If safe and feasible, MR personnel should accompany emergency personnel into the MNC to ensure the safety of emergency responders in the vicinity of the Scanner Room.
- 10) If it may be necessary for emergency responders to bring MR Unsafe equipment into the Scanner Room, a decision to quench the MR magnet should be seriously considered to protect the health and lives of the emergency responders and any others in Zone 4.

If you encounter smoke while evacuating, get close to the floor where there is less smoke and the air is coolest. With the back of your hand, feel the door. If the door is cool, open it slowly. If the door is hot, or if you detect smoke on the other side, do not open it, unless a person on the other side is seeking assistance. Seek another way out. If you cannot get out, shelter in a safe place. Call emergency response, yell for help, or text a friend. Attempt to make yourself visible to responding authorities.

#### **Fire Alarm Protocol**

- 1) Remain calm.
- 2) Immediately remove the participant from scanner.
- 3) Close and lock the Scanner Room door.
- 4) Evacuate the building with the research MR Personnel, participant, and all others present.
- 5) Notify the MR Physicist.

#### **Blackout Power Outage Protocol**

- 1) Remain calm.
- 2) If the power is off and does not return for <u>more than 30 seconds</u>, immediately end the scanning session, even if the Uninterrupted Power Supply Unit (UPS) allows you to continue scanning.

- The UPS is in place ONLY to allow time to safely shut down the scanner.
- Do NOT shut down the scanner until the participant has been helped safely out of the Scanner Room.
- 3) Let the participant know over the intercom that everything is okay, but the session will end early. Inform them that you will be coming into the room to get them out of the scanner, but they must stay in place.
  - o If the UPS is powering the scanner, you may remove the participant from the scanner using the electronic table buttons.
  - o If the power is lost, decouple the scanner table from its motor by pulling out the brake lever under the right side of the scanner table. Then pull the table out of the scanner bore by lip of the table. Do NOT pull the immobile rail at the foot of the table (See **Table Stop Protocol**). Do NOT allow the participant to move from the table before the MR Safe ladder is in place.
- 4) Even if the lights are still on, as a precaution, turn on the MR Unsafe flashlight on the back desk and place it on the desk in the direction of the Scanner Room. Do NOT bring the flashlight into the Scanner Room!
- 5) Escort the participant to Zone 3 so the research MR Personnel may use their cell phone light to escort the participant out of Zone 3. They can retrieve their belongings but should leave the building as quickly as possible.
- 6) Put the scanner into "home position," if possible.
- 7) Close and lock the Scanner Room door.
- 8) Shut the scanner down normally, if possible.
- 9) Turn off other Zone 3 equipment, if possible.
- 10) Ensure the MNC has been evacuated.
- 11) Leave the MNC.
- 12) Notify the MR Physicist, as power interruptions to the scanner and its equipment can have damaging effects.
- 13) Notify the MNC Director of Operations and Finance and Facilities Management: 301-405-2222, or campus phone extension: 5-2222. Dial 9 first for calls from campus phones to non-campus lines.

#### Brownout (i.e., Partial) Power Outage Protocol

- 1) Remain calm.
- 2) If the power returns after less than 30 seconds the scanning session may continue.
- 3) If the experiment was interrupted due to the outage, let the participant know over the intercom that everything is okay.
- 4) Notify the MNC MR Physicist of the brownout as soon as feasible.

#### **Phantom Fluid or Scanner Coolant Spills Protocol**

Do not use damaged or leaking phantoms!

- 1) Avoid skin contact with fluid leaking from a phantom or the scanner.
- 2) If fluid has the potential to become electrified (e.g., near the scanner or an outlet), do not attempt to clean it up.

- 3) Hit the EPO button if the fluid is in danger of contacting the scanner.
- 4) Contact the MR Physicist and Facilities Management: 301-405-2222, or campus phone extension: 5-2222. Dial 9 first for calls from campus phones to non-campus lines.
- 5) If the MR Physicist indicates it is safe to clean up the fluid, put on disposable protective gloves and goggles or a face mask, if available.
- 6) Absorb fluid with absorbent material (e.g., towels, sand, sawdust).
- 7) Place absorbent material and the leaking phantom in a plastic bucket. You will find a bucket under the kitchen sink.
- 8) Contact the Department of Environmental Safety, Sustainability, and Risk: 301-405-3960, or 5-3960 from a campus phone for disposal and additional cleanup advice. Dial 9 first for calls from campus phones to non-campus lines.
- 9) Change out of contaminated clothing.
- 10) Wash hands thoroughly with soap and water.
- 11) Contact Siemens Service with additional questions, if necessary.

#### First Aid Protocol for Contact with Phantom Fluid or Glycol

- Skin Contamination
  - 1) Immediately remove contaminated clothing.
  - 2) Immediately wash skin with soap and water.
  - 3) Immediately consult a physician.
- Eye contamination
  - o Immediately consult an ophthalmologist.
- Ingestion
  - 1) Drink plenty of water and induce vomiting.
  - 2) Immediately consult a physician.
- Inhalation
  - 1) Immediately find fresh air.
  - 2) Immediately consult a physician.

#### **Flooding Protocol**

Whether from roof failure, burst pipes, storm surges, or rising water levels, all MRI facilities are susceptible to water damage. It only takes a small amount of water to incapacitate or destroy the MRI scanner or its equipment.

- 1) If fluid has the potential to become electrified (e.g., near the scanner or an outlet), do not attempt to clean it up.
- 2) Hit the EPO button if the fluid is in danger of contacting the scanner.
- 3) Contact the MR Physicist and Facilities Management: 301-405-2222, or campus phone extension: 5-2222. If the MR Physicist cannot be reached, call Siemens: 1-800-888-7436. Dial 9 first for calls from campus phones to non-campus lines.

#### **Building Lockdown Protocol**

- 1) Remain Calm.
- 2) Close Zone 3 door (it will lock automatically).
- 3) Remove participant from scanner.
- 4) Close and lock the Scanner Room door.
- 5) Shelter in place in the Equipment Room until notified that it is safe to leave the building.

#### **Active Shooter Protocol**

- 1) If a shooter is not inside of the MNC, shelter in place.
- 2) Remain Calm.
- 3) Close Zone 3 door (it will lock automatically) and turn off the lights.
- 4) Remove participant from scanner.
- 5) Close and lock the Scanner Room door.
- 6) If there is time, turn off the entrance, lobby, and lobby office lights.
- 7) Call emergency response.
- 8) Keep everyone sheltered in place in Zone 3 until notified that it is safe to leave the building.

#### If a shooter is encountered directly:

#### Run:

- 1) Immediately run away from the gunman or from sounds of gunfire.
- 2) Get to a safe place and call UMD Police at 301-405-3555.

#### Hide: If you can't run...

- 1) Close, lock and block the door.
- 2) Turn off lights and silence phones.
- 3) Hide under a desk, in a closet or behind a wall or furniture.

#### Fight: If you can't run or hide...

- 1) Find anything that can be used as a weapon.
- 2) Attack the shooter when possible.

#### Theft or Break-In Protocol

• Contact the MNC Director of Operations and Finance and provide a detailed report.

#### Accidents, Injuries, and Incidents Reporting Protocol

Any accidents involving the MR scanner which cause injury to an individual or research participant must be reported to the MNC Director of Operations and Finance and MR Physicist by the researcher conducting the study.

If an accident or injury occurs that is not related to an MRI study, then the MR Operator or individual on site who is responsible should report it to the MNC Director of Operations and Finance.

The accident, injury, or incident may need to be reported to the University of Maryland and the Institutional Review Board(s).

#### APPENDIX 1: SAFETY DESIGN OF MNC FACILITY

According to safety and human factors engineering principles, multiple safety strategies must be adopted to be effective. This approach is sometimes termed defense in depth.

The safety strategies outlined in the main body of this standard operating procedures MR safety manual include people-oriented strategies for policies and training, for instance, policies that restrict personnel access, specialized training and drills for MR Personnel, and warning labels for devices to be brought into Zone 3 and Zone 4 regions. Defense in depth; however, is more than just by preventing MR Unsafe items from becoming missiles or screening out participants with hazardous implanted devices.

The MNC has also adopted strategies of safety-oriented design which support the other safety strategies by making them easier to follow. This appendix includes descriptions of design organization of the many MR suite functional areas which increase compliance and encourage safety and best practices by improving the flow of participants, other untrained individuals, Non-MR Personnel, and equipment and devices.

For example, having a private area for participant screening interviews will make it more likely that participants will disclose sensitive types of implants. Another example of designing for safety is to include dedicated space and temporary storage in Zone 2 for the belongings of all visitors. The guidance that follows is designed to address many of these issues, which directly impact safety within the MR suite.

#### 1) Participant Consenting, Screening, Debriefing, & Payment Areas (Zones 1 and 2)

Reviewing the MNC MR Safety Screening Form and MR Hazard Checklist requires discussing confidential personal information. To facilitate full and complete disclosure of medical history, MR screening should be conducted in Zones 1 or 2, in an area that provides auditory and visual privacy for the participant and their parent/guardian.

#### 2) Physical Screening and Participant Changing/Gowning Rooms (Zone 2)

All untrained individuals and Non-MR Personnel who plan to enter Zone 3, as well as all objects which MR Personnel plan to bring into Zone 3, must be physically screened for the presence of ferromagnetic materials that may pose threats in the MR environment. Physical screening should consist of removal of all jewelry, all metallic objects (whether ferromagnetic or not), and prostheses. Physical screening may also include changing out of street clothes into MNC-provided gowns or scrubs, if necessary. Participant and other untrained individuals' belongings should not be retrieved or accessed from Zone 2 until they have completed the MR scanning protocol and will not be re-entering Zones 3 or 4.

Zone 2 is the designated area for identifying, removing, and temporarily storing any items which the participant and other untrained individuals may have brought with them to the MNC which might pose threats in the MR environment. The identification process includes determining clothing fiber composition, looking over clothing for loose metal,

ensuring that no metallic fasteners or reinforcing devices in the clothing are in contact with the skin, and lastly, searching all pockets for items. Participants and those accompanying them who must change out of their street clothes and into MNC provided gowns or scrubs are to use the Locker Room in the Mock Suite or the Zone 2 restroom.

The ACR recommends the use of ferromagnetic metal detectors for participants and those who may accompany them prior to passing through the controlled point of access into Zone 3. Ferromagnetic or metal detecting systems have been demonstrated to be effective adjuncts to the MR safety screening process; however, they are never to be used in place of the previously stated physical screening steps.

#### 3) Transfer Area/Ferrous Quarantine Storage (Zone 2)

Participants who arrive with a skateboard, scooter, hoverboard, crutches, wheelchair, walker, portable oxygen tank, or other appliance that may be unsafe in the MR environment should secure these items in a Zone 1 or Zone 2 preparatory room, ideally out of sight, if possible. These modes of transportation and types of devices should not be kept in any closets in which MNC supplies are housed. Participants who require a device for mobility (e.g., crutches, walker, wheelchair, or motorized scooter) may use the MNC's MR Safe wheelchair to move from Zone 2 to Zones 3 and/or 4.

#### 4) Access Control (Zones 3 and 4)

Access to Zone 3 must be physically secured from Zone 2 at all times. The Zone 3 door should **never** be propped open unless Level 2 MR Personnel are present in Zones 3 or 4. Similarly, the Zone 4 door should always be closed unless Level 2 MR Personnel are currently inside Zone 4.

#### 5) Lines of Sight/Situational Awareness (Zone 3)

Trained Level 2 MR Personnel are arguably the single greatest safety resource of MR facilities. These individuals should have a direct line of sight of all entrances and exits to Zones 3 or 4. The MR Operator (also Level 2 MR Personnel has a direct line of site from their MR system console to both the Zone 3 and Zone 4 entrances, as well as a direct line of site to the participant in the MR scanner bore through the RF-shielded window.

#### 6) Emergency Resuscitation Equipment (Zones 2, 3, and 4)

The MNC has provisions for emergencies and resuscitation of participants. The MR Safe fire extinguisher is located in Zone 3, to the right, as one walks through the Zone 3 entrance; the first aid supplies are located to the left of the Zone 3 entrance on the counter. The AED is on the wall, on the left side of the Zone 2 hallway, between the Mock Suite and the restroom. The MR Safe gurney is in Zone 4, to the right of the MR scanner as one enters Zone 4.

#### 7) Cryogen Safety (Zone 4)

Cryogenic liquids are used in superconductive MR environments. The physical properties of these cryogenic liquids present significant potential safety hazards. If exposed to air at room temperature, these cryogenic liquids will rapidly boil off and expand into a gaseous state. This produces several potential safety concerns, including:

- asphyxiation potential as cryogenic gases replace oxygenated air
- frostbite considerations at the exceedingly low temperatures of these cryogenic liquids
- fire hazards
- pressure considerations within Zone 4

Failure of cryogen quench pipe assemblies may lead to considerable quantities of cryogenic gases being inadvertently discharged into Zone 4 (the Scanner Room). If released into Zone 4, the cryogens thermally expand and could positively pressurize the magnet room and entrap persons inside until the pressure is equalized.

Although it has proven effective in life-threatening situations, breaking the observation window between Zones 3 and 4 should not be advocated as a primary means of relieving or equalizing Zone 4 pressure in a quench situation, as RF-shielded windows can be very difficult to break.

The MNC has a magnet quench escape hatch through which persons inside the Magnet Room could evacuate into Zone 3 in the event of an extreme pressure build-up. It is located between the MR system console and the Magnet Room door. The Magnet Room also has several open waveguides which would help relieve at least some pressure.

#### 8) MR Conditional Devices (Zone 4)

The normal or safe operation of many devices designed for use in the MR environment may be disrupted by exposure to conditions exceeding the device's conditional rating thresholds. All MR Conditional devices that may be brought into Zones 3 or 4 should be identified and labeled with the approved conditional rating for static field (B0) and spatial field gradient (dB/dx) exposure, as well as RF power rate or duration limitations, and if applicable, gradient dB/dt-tested exposure limits. MR Conditional devices may be safe at one specific static magnetic field strength but unsafe at higher *or* lower field strength. Additionally, MR Conditional devices may be safe in one region of the magnet but not in another. If not kept outside of the magnet region(s) with equal or higher field strength, potentially harmful torque and/or translational forces could result. Projectile incidents of conditional devices have been reported when all conditions have not been met.

The MR Physicist is responsible for confirming proper static magnetic field and static gradient field labeling of all new MR Conditional devices and equipment (e.g., monitoring devices, participant response buttons, cables, etc.), as well as evaluating equipment returning from repair. This involves using the handheld magnet and the metal

detecting wand. Documentation from the vendor and peer-reviewed MR testing may also be consulted when evaluating new equipment.

Any devices, implants, or materials brought into Zone 4 which may contain metallic components must be clearly labeled MR Safe, MR Conditional, or MR Unsafe.

## APPENDIX 2: MNC SAFETY SCREENING FORM

(Form on the following page.)

# MNC MR Safety Screening Form

Date of Birth (mm	/dd/yyyy): H	leight: Weight:	Age: Subject ID:
Sex: DFemale DN	Male Other:	Pronouns (optional):	
Zip Code:	Phone (Cell):	City: Phone (Home/W	State:
	180 2 (8)	ircle and leave blank to discuss with t	e pr
MR Operator.			Please mark the location of a
Please indica	te if you have or have not	had the following:	implant, device, metallic fore
	and American	. Had the following.	body, tattoo, or piercing on o
<ul> <li>□Yes □No</li> </ul>	Previous MRI examination		inside your body.
Area of Body	Date	Facility Name & Location	
	, , ,	127	
2,449k tw. 6 to to - 100 to 112 Network			
<ul> <li>□Yes □No</li> </ul>	Surgery or medical procedu	re of any kind (If yes, list <b>all</b> )	THE PARTY NAMED IN THE PARTY NAM
Surgery & Area o	of Body Date	Facility Name & Location	(A)
. 1. 4. 4. 1. 1 <del>. 1.</del> 41. 1. F. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.			
			NO NO ARE
			_   \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
			_ 11 1
			_ /3
- □Yes □No	Is there a possibility you are p	oregnant?	
<ul> <li>□Yes □No</li> </ul>	Have you had seizures or a move	ement disorder? If yes, describe:	
<ul> <li>□Yes □No</li> </ul>			
• □Yes □No	Are you claustrophobic?		
		ring your MR scan and may interfer	e with the MR exam.
You must provi	de a "Yes" or "No" answer for	every item.	
П П			
- □Yes □No	Injury by a metal object or for	reign body (e.g., shrapnel, BB, bucks	shot, bullet, metal shards or splinters)
If yes, explain: _		10000	<del></del>
<ul> <li>□Yes □No</li> </ul>	Eye injury by a metal fragment or object		
Tf was did was	selt medical attention 2 TVac TN	To If yes, describe what was found, how	ritums found and horseit une communate
n yes, aid you se	ea medical alternion? Lifes LIN	n yes, describe what was found, now	vit was found, and now it was removed:
n -	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	94 (1 May 1	77 30
- □Yes □No	Non-removable dental work	or orthodontia (e.g., braces, permane	ent retainer, crowns, dental implants)
If yes, explain: _		1132 33	
- □Yes □No	Spinal fusion procedure If	yes, describe:	
<ul> <li>□Yes □No</li> </ul>	Endospobu az adaman	ithin the last 8	
- ∐Yes ∐No	Endoscopy or colonoscopy w	iumi die iast 3 months	
Do you currently.	or have you EVER HAD any o	of the following surgically implanted :	medical devices?
<ul> <li>□Yes □No</li> </ul>	Any type of electronic, mecha	anical, or magnetic implant	
If you describe			

# Safety Screening for Magnetic Resonance (MR) Procedures

The following items may be harmful to you during your MR scan and may interfere with the MR exam. You must provide a "Yes" or "No" answer for every item.

Do you currently,	or have you EVER HAD any of the following surgically implanted medical devices?		
- □Yes □No	Cardiac pacemaker, defibrillator, catheter, prosthesis, clamp, or other cardiac implant If yes, describe:		
• □Yes □No	Artificial heart valve, venous umbrella, aortic or vascular clip, or vascular access port		
• □Yes □No	Aneurysm clip or other brain clip		
• □Yes □No	Neurostimulator, DBS (deep brain stimulator), diaphragmatic stimulator, vagus nerve stimulator, bone growth stimulator, spinal cord stimulator, or any other biostimulator  If yes, list:		
• □Yes □No	Any type of internal electrodes or wires		
• □Yes □No	Implanted drug pump (e.g., insulin, badofen, chemotherapy, pain medication)		
• □Yes □No	Spinal fixation device		
- □Yes □No	Any type of coil, filter, or stent (vascular or other)  If yes, describe:		
• □Yes □No	Cochlear, otologic, or other ear implant		
• □Yes □No	Joint replacement If yes, describe:		
• □Yes □No	Penile implant		
• □Yes □No	Artificial eye		
• □Yes □No	Eyelid spring or weight, or ocular/lens implant   If yes, describe:		
• □Yes □No	Any type of implant held in place by a magnet    If yes, describe:		
• □Yes □No	Any type of surgical clip, suture, or staple   If yes, describe:		
• □Yes □No	Shunt (spinal or ventricular) If yes, describe:		
• □Yes □No	Artificial limb If yes, describe:		
• □Yes □No	Tissue expander		
• □Yes □No	IUD If yes, manufacturer and model:		
<ul> <li>□Yes □No</li> </ul>	Surgical mesh If yes, describe:		
• □Yes □No	Radiation seeds		
<ul> <li>□Yes □No</li> </ul>	Hormone-releasing implant		
<ul> <li>□Yes □No</li> </ul>	Any other implanted items (e.g., pins, screws, nails, rods, plates, wires, electrodes)		
Do you currently l	have any of the following removeable medical devices?		
• □Yes □No	Hearing aid		
■ □Ves □No	Artificial eve		

# Safety Screening for Magnetic Resonance (MR) Procedures

The following items may be harmful to you during your MR scan and may interfere with the MR exam. You must provide a "Yes" or "No" answer for every item.

Do you currently l	nave any of the following removable medical devices?	
<ul> <li>□Yes □No</li> </ul>	Removeable drug pump (e.g., Insulin, Badofen, Neulasta) If yes, describe:	
• □Yes □No	Any type of ear or head implant   If yes, describe:	
• □Yes □No	Any type of removable implant held in place by a magnet  If yes, describe:	
- □Yes □No	Any type of removable clip or staple  If yes, describe:	
• □Yes □No	Medication patch (e.g., birth control, nicotine, nitroglycerine)  If yes, describe:	
• □Yes □No	Artificial limb  If yes, where and what kind:	
<ul> <li>□Yes □No</li> </ul>	Removable dentures, false teeth, or partial plate  If yes, describe:	
<ul> <li>□Yes □No</li> </ul>	Diaphragm, pessary, or bladder ring	
• □Yes □No	Have you recently ingested a pill cam? If yes, date of ingestion:/	
Do you have any	of the following on or in your body?	
• □Yes □No	Body piercings (regardless whether made of metal, plastic, or glass)  If yes, location:	
- □Yes □No	Tattoo If yes, for each, describe the image, the date it was received, and the name and location of the tattoo shop to the best of your ability:	
• □Yes □No	Tattooed eyeliner, tattooed lipliner, tattooed eyebrows, or similar If yes, date of tattoo://  Type of tattoo, and name and location of tattoo shop:	
<ul> <li>□Yes □No</li> </ul>	Jewelry	
• □Yes □No	Makeup, lipstick, eyeliner, eyeshadow, lotions, or sunscreen  If yes, describe type and location(s):	
<ul> <li>□Yes □No</li> </ul>	False eyelashes	
<ul> <li>□Yes □No</li> </ul>	Magnetic nail polish	
• □Yes □No	Hair dye, hair product, hair spray, hair gel, hair wax  If yes, describe:	
• □Yes □No	Wig, weave, braids, hair extensions, or hair piece  If yes, describe:	
- □Yes □No	Electronic monitoring or tagging device or equipment	
<ul> <li>□Yes □No</li> </ul>	Fitness tracker or biomonitor (e.g., Fitbit, Apple Watch)	

### Safety Screening for Magnetic Resonance (MR) Procedures

<ul> <li>□Yes □No</li> </ul>	Do you have any other type of surgically implanted medical devices, removable medical devices, or
	personal items not covered above?
	If yes, describe:

#### Pre MR environment entry instructions

- You will be provided mandatory hearing protection before the MR scans begin. The earplugs or headphones provided
  are required to protect your hearing from the loud acoustical scanner noises.
- 2. All jewelry, ear-piercings, and body piercings must be removed, regardless of material or location on your body.
- All hair pins, bobby pins, hair clips, barrettes, hair ties, scrunchies, or other hair accessories must be removed, whether
  they contain metal or not.
- 4. Belts, keys, coins, wallets, nail clippers, safety pins, paper clips, money clips, and pocket knives must be removed.
- All dentures, partial plates, and false teeth must be removed.
- 6. Hearing aids must be removed.
- Eyeglasses must be removed.
- Contact lenses which have sensors (e.g., Triggerfish, or are cosmetic or decorative (circle lenses, big eye lenses, colorchanging) must be removed.
- 9. Watches, cell phones, fitness trackers, and pagers must be removed.
- 10. Cards with magnetic strips (e.g., credit and debit cards, hotel keys, university IDs) must be removed.
- 11. If you are unable to remove any of the above items, please notify the MR Operator.
- 12. The MR Operator will visually assess your clothing for signs of metallic treatment. This does not mean that your clothing does not have metallic threads or treatments. It is up to you to bring clothing safe for the MR scanner. The research lab is tasked with reminding you not to wear athletic, yoga, or athleisure clothing, especially if it has a sheen to it, if it is brand name, or if it is advertised as moisture-wicking, antimicrobial or antibacterial, compression, thermal, cooling, breathable, HeatGear, ColdGear, etc.

If the MR Operator believes your clothing may contain metallic threading or may be treated with metallic solutions, you will be offered scrubs or gowns if they are available. If alternatives are not available or you are unwilling or unable to change into the alternative item(s), the scheduled scan will not proceed.

	ntents of this form. I had the opportunity to ask any and all questions I had abou ation is correct to the best of my knowledge.
Participant signature:	
Participant printed name:	
Date://	
	20 273
Parent/guardian/caretaker signature (if a	
Parent/guardian/caretaker printed name	(if applicable):
Date://	
Level 2 signature:	70.01 - 10 - 10 - 10 - 10 - 10 - 10 - 10
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