

**The WSU Center of Neuroimaging and
Neuro-Evaluation of Cognitive Technologies
(CoNNECT)**

MRI Safety Manual

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1. Introduction

“First and foremost, the protection of health and safety is a moral obligation. An expanding array of federal, state and local laws and regulations makes it a legal requirement and an economic necessity as well. In the final analysis, laboratory safety can be achieved only by the exercise of judgment by informed, responsible individuals. It is an essential part of the development of scientists that they learn to work with and to accept the responsibilities for the appropriate of hazardous substances.”¹

Our university community is responsible for ensuring that all research and related activities are conducted with minimal hazard to employees, students and the community. The procedures described in this manual are elements essential to our program. Anyone using equipment and facilities of this institution is expected to follow accepted procedures, to report all accidents promptly and bring to their supervisor’s attention any unsafe conditions or practices.

This manual provides members of the Wright State University (WSU) community with information on the inherent risks associated with the Magnetic Resonance Imaging (MRI) at the WSU Center of Neuroimaging and Neuro-Evaluation of Cognitive Technologies (CoNNECT) located in the Neuroscience Engineering Collaboration (NEC) building at WSU’s Dayton Campus. This manual defines suitable safeguards and procedures for use of the MRI. Placing these policies and procedures into practice is the responsibility of those not only in administrative positions, but in all positions throughout our organization. It is essential that everyone be thoroughly familiar with this manual and knows who to ask for additional advice and training.

The use of Magnetic Resonance Imaging (MRI) presents known safety hazards. MRI Safety Guidelines have been developed so that investigators, researchers, students, colleagues, study participants, and associated equipment remain safe in the magnetic environment. All personnel working within the magnetic environment are required to complete MRI safety training. The WSU CoNNECT Governing Board and the Department of Environmental Health and Safety have developed this guide of general MRI safety information for Research MRI Users.

2. Purpose

The purpose of this MRI Safety Guidelines is to provide a resource for continued safe MRI practices within WSU CoNNECT research community. The WSU CoNNECT Governing Board developed the MRI Safety Guidelines based on locally accepted standards and the internationally accepted recommendations of the American College of Radiology (ACR). The initial Blue Ribbon Panel of the ACR, lead by Emanuel Kanal, M.D., FACR, first published recommendations in 2002 with revised information in 2004 and 2007. In 2020 the ACR Committee on MR Safety published revised guidance: ACR Manual on MR Safety, was published and is used as the primary reference for the MRI Safety program at the WSU CoNNECT.

The 2020 recommendations are incorporated into daily practice and policy here in light of continuing reports of accidents in the magnetic environment involving both equipment damage and serious personal injury, including death within the MR community. The MRI Safety Guidelines are reviewed on a regular basis, modified as needed and posted on websites for the Department of Environmental Health and Safety (<https://www.wright.edu/facility-operations/laboratory-and-research-safety>) and the WSU CoNNECT (www.wright.edu/connect-lab).

The 2020 ACR Manual on MR Safety recommends that:

- All MRI sites should maintain MR safety policies.
- The MRI Safety Guidelines should be reviewed concurrently with the introduction of any significant changes in safety parameters of the MR environment and updated as needed.
- Site administration is responsible to ensure that the MRI Safety Guidelines are implemented and adhered to at all times by all site personnel.

¹ National Research Council, 1981. Prudent Practices for Handling Hazardous Chemicals in Laboratories, Washington, D.C., National Academy Press, p. 6

- Any and all adverse events, MR safety incidents or “near incidents” are reported to the WSU CoNNECT Director and MR Scientist and used in continuous quality improvement efforts.

The WSU CoNNECT suggests action consistent with the ACR recommendations to prevent accidents and injuries in the MRI suite. The risk reduction strategies include reference to the ACR guidelines.

3. Definitions

3.1. ACR Definitions of Non-MR and MR Personnel

3.1.1. Non-MR Personnel:

Non-MR Personnel are individuals who have not successfully completed educational efforts regarding MR safety issues defined within this manual (see Section 4.2). These individuals are most commonly patients/subjects but may also be visitors, students, staff or faculty. Specifically, *Non-MR Personnel* will be the terminology used to refer to any individual who has not within the previous 12 months successfully undergone the designated formal MR safety education defined within this manual necessary to qualify as MR Personnel.

3.1.2. Level 1 MR Personnel:

Level 1 MR Personnel will be the terminology used to refer to any individual who has completed the facility’s MR basic safety educational requirements (see Section 4.2.1) to ensure that they would not constitute a danger to themselves or others in the MR environment.

3.1.3. Level 2 MR Personnel:

Level 2 MR Personnel will be the terminology used to refer to any faculty, staff or affiliate who has completed advanced safety training and education (see Section 4.2.2) in the broader aspects of MR safety issues or who the MR Director has deemed comparably trained (e.g., ACR certified MR Technologist). Level 2 MR Personnel have the authority by the Governing Board to stop any procedure they feel exceed safe practices.

3.2. MRI Zones

The WSU CoNNECT will define 4 zones in accordance with ACR recommendations (Figure 1). Zones II, III and IV will be demarcated and clearly indicated as being potentially hazardous.

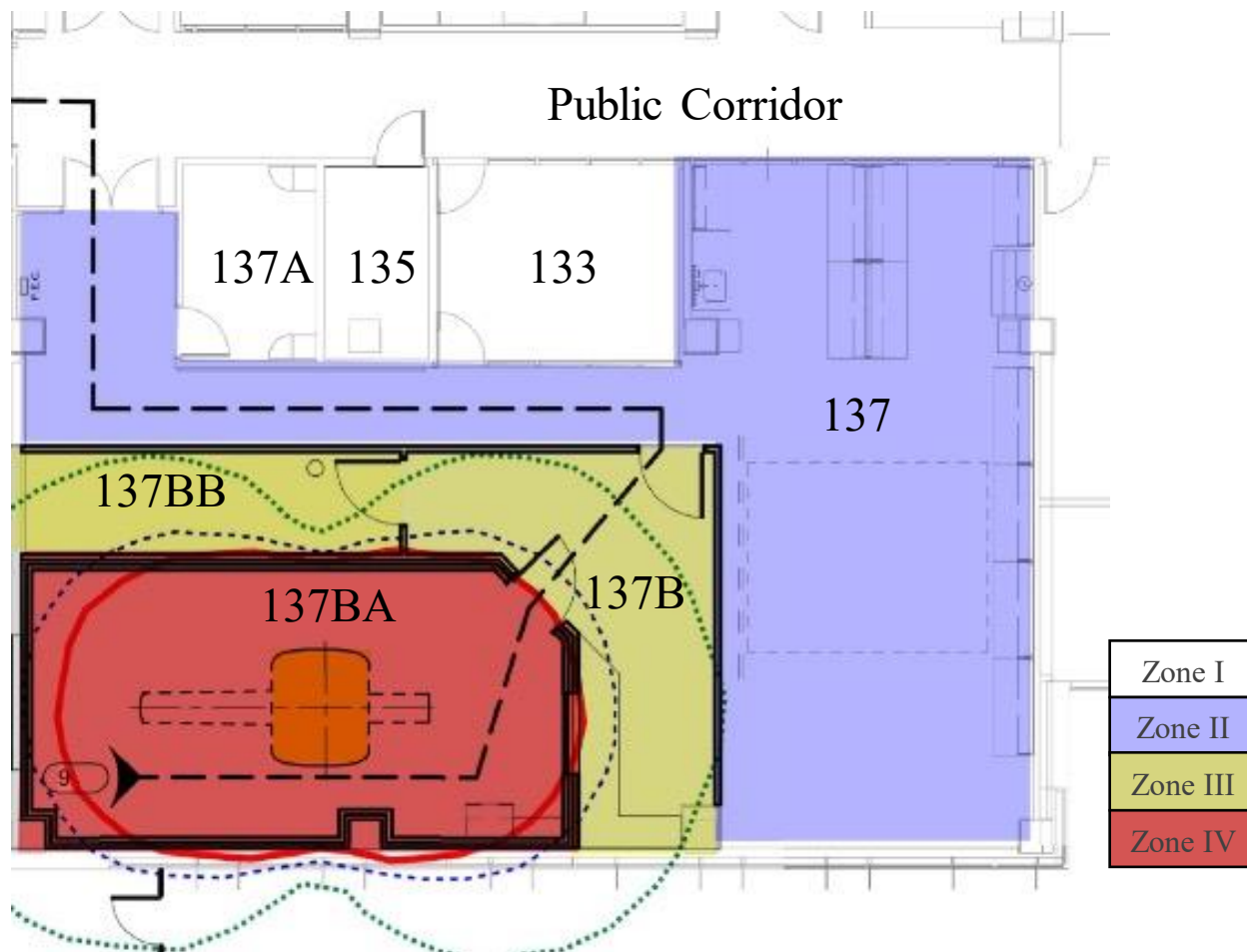


Figure 1. Floor plan indicating the MRI zones. Public spaces and rooms within the NEC other than 137 are classified as uncontrolled, Zone I. NEC 137 is accessible via the public corridor and is classified as Zone II. Free movement is allowed within Zone II. NEC 137B requires screening prior to entry and, thus, is considered Zone III. NEC 137BA is Zone IV with strict access restrictions to personnel and equipment. Free movement within NEC 137B, 137BB, and 137BA (Zones III and IV) is not allowed, and requires either a Level 1 MR Personnel status or a Level 2 MR Personnel escort.

3.2.1. Zone I

This region includes all areas that are freely accessible to the general public. This area is outside of the MR environment itself. This area can be freely traversed by patients/subjects, visitors, students, staff and faculty.

3.2.2. Zone II

This region is the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled Zones III and IV. Patients, visitors, students, staff and faculty can move freely throughout Zone II without the need to be screened prior to entry. Patient/Subject preparation is to take place in Zone II, including screening and gowning (if necessary).

3.2.3. Zone III

This region poses serious risk including injury or death to unscreened Non-MR Personnel or ferromagnetic objects/equipment due to interactions between individuals/equipment and the MR scanner. Access to Zone III by Non-MR Personnel must be controlled by, and entirely under the supervision of, Level 2 MR Personnel. Entry to Zone III will only be granted after a Level 2 MR Personnel has reviewed the WSU CoNNECT screening form and deemed a safe entry. Non-MR Personnel must be under the immediate supervision of and in visual contact with an individual of Level 2 MR Personnel throughout Zones III and IV. Level 1 MR Personnel can traverse Zones III and IV unsupervised;

however, a Level 2 MR Personnel must grant initial access and be present while the Level 1 MR Personnel is within Zone III or IV.

Zone III will be card-swipe access controlled and limited access will only be granted to individuals with an active Level 2 MR Personnel status.

3.2.4. Zone IV

Zone IV is synonymous with the MR scanner room itself. All guidelines of Zone III are effective for Zone IV. Zone IV is located within Zone III and is only accessible via Zone III. Zone IV will be clearly labeled as being potentially hazardous because of the presence of very strong magnetic fields. The entrance to Zone IV will be within the direct observation and control of an individual with Level 2 MR Personnel status. The door to Zone IV will always remain closed except when entering or leaving the zone.

3.3. MR Medical Director

The WSU CoNNECT MR Medical Director will be a physician or radiologist who possesses intimate knowledge of the MRI including its safety concerns. The MR Medical Director will ensure medically-relevant policies and procedures are implemented.

3.4. MR Director

The WSU CoNNECT MR Director will be an individual who possesses intimate knowledge of MRI including its safety concerns, physics and operation. The MR Director will oversee general operation of the MRI and will be responsible for all safety issues, training and approval of personnel classifications defined above.

3.5. MR Scientist

The WSU CoNNECT MR Scientist will be an individual who possesses intimate knowledge of MRI including its safety concerns, physics and operation. The MR Scientist will oversee general quality assurance of the MRI.

3.6. Governing Board

The WSU CoNNECT will have a Governing Board to develop, review and implement MRI laboratory standards and practices. The MR Director shall chair the Governing Board. The Governing Board may include staff and faculty members from WSU but also external constituents from the US Air Force and US Navy. This Governing Board meets regularly to review policies and procedures, and to review any safety incidents.

3.7. MR Safety Officer

The WSU CoNNECT MR Safety Officer will have the knowledge and experience to ensure implementation of the Safety Program. The primary function is to be a safety point of contact for all faculty, staff and affiliates of the WSU CoNNECT. This position has the authority to immediately cease unsafe activities or activities that are not compliant with applicable rules and regulations. Any safety concerns from the MR Safety Officer will be immediately reported to the Governing Board at which time a course of action will be determined. Actions from the Governing Board may include a full stop of all research, revocation of MR Personnel classifications or an immediate change in policies and procedures.

3.8. MR Research User

The MR Research User may be a Principal Investigator (PI) who has an Institutional Review Board (IRB) approved protocol and utilizes the WSU CoNNECT MRI scanner for research or pilot testing purposes. MR Research Users may also be faculty, staff or affiliates who utilize the WSU CoNNECT for research and non-research applications (e.g., educational purposes). An affiliate, student, staff member, or research assistant for whom the PI, faculty, staff or affiliate is responsible is also considered a MR Research User. If the MR Research User is engaged in research activities, the IRB approval must be provided to the MR Director prior to engaging research activities. Only MR Research Users with approved protocols are allowed to schedule MRI scanner time for research studies.

3.9. Patient/Subject

The patient/subject is a human research participant who is placed into the MRI scanner for research purposes. The patient/subject must complete and sign both IRB consent and MRI Screening Form prior to the MRI scan. The patient/subject must be treated and cared for within all institutional and federal guidelines and regulations.

3.10. MR Operator

The MR Operator is an individual who is a Level 2 MR Personnel and has been specially trained in the operation of the MRI scanner at the WSU CoNNECT. Undergraduate students or volunteers are not eligible for MR Operator training.

3.11. MRI Scanners

The available MRI Scanner(s) as of 02/25/2022 at the WSU CoNNECT is:

- Philips Achieva dStream 3.0T (Figure 2)



Figure 2. WSU CoNNECT's Philips dStream Achieva 3.0T MRI system installed in NEC 137.

4. Standard of Practice at the WSU CoNNECT

It has been reported by other facilities that any of the MRI related injuries and the few fatalities that have occurred were the apparent result of failure to follow safety guidelines or the use of inappropriate or outdated information. Thus, it is required that all MR Research Users, patients/subjects, visitors, etc. only gain entry to Zone III and Zone IV when at least one Level 2 MR Person is present in Zones III or IV.

4.1. Staffing Requirements

To maintain safe laboratory practice, at least one Level 2 MR Personnel within the WSU CoNNECT must be in visual contact with the patient/subject (and any non-MR Personnel) for all MRI scanning during normal work hours, being Monday through Friday, 8am to 5pm. After normal work hours, weekends and holidays, a minimum of two MRI safety trained individuals (at least one Level 1 and one Level 2) must be present with the patient/subject.

4.2. Safety and Operations Training

The MR Medical Director, MR Safety Officer, MR Director, and MR Scientist are responsible for developing and overseeing any required safety and operations training. Approval of Level 1, Level 2 or MR Operator status must be approved by one of these individuals.

4.2.1. Basic MR Safety Training

All MR Research Users planning to regularly enter the MRI suite (Zones III or IV) for the purposes of conducting research must complete Basic MR Safety Training. Basic MR Safety Training will be completed on-site by the MR Safety Officer, MR Scientist, MR Director, or MR Medical Director. This training consists of a presentation that includes viewing of a safety video and a simple quiz. A 100% on the quiz is required to obtain Level 1 MR Personnel status. Alternatively, basic MRI safety training may be completed using the Level 1 MR Safety Training available at <https://www.appliedradiology.org/mrisafety>. Individuals completing the Basic MR Safety Training will be classified as Level 1 MR Personnel. After initial training, yearly refresher courses will be required to maintain Level 1 MR Personnel status. Records of completion of training shall be retained per Section 4.3.8 below.

4.2.2. Advanced MR Safety Training

For MR Research Users seeking to become MR Operators or Level 2 MR Personnel, Advanced MR Safety Training will be completed on-site by the MR Safety Officer, MR Scientist, MR Director, or MR Medical Director. This training course will be more detailed in coverage of safety procedures, human subject screening procedures and emergency procedures than basic MR safety training. Training will end with a quiz requiring 100% to obtain Level 2 MR Personnel status. Individuals seeking to obtain Level 2 MR Personnel status must either have at minimum a Bachelor's Degree in a relevant field. The MR Director may waive training if the individual has a MRI Technologist certification from the American Registry of Radiologic Technologists (ARRT) or the American Registry of Magnetic Resonance Imaging Technologist (ARMRIT). An alternative to this training may be completed using the Level 2 MR Safety Training available at <https://www.appliedradiology.org/mrisafety>. After initial training, yearly refresher courses will be required to maintain Level 2 MR Personnel status. Records of completion of training shall be retained per Section 4.3.8 below.

4.2.3. MRI Operation Training

MRI Operation Training may be offered to MR Research Users with a Level 2 MR Personnel status who are interested in expanding their knowledge of MRI operations; however, those without Level 2 status such as undergraduates may complete the training on their own but will not receive this designation. The training may consist of off-site materials including presentations and videos and on-site hands-on learning. Additionally, training will require at least 100 hours of on-site learning and observation. Training will commence with a hands-on test and in-person evaluation of skills proctored by the MR Medical Director, MR Safety Officer, MR Director, or MR Scientist. No annual training will be required to maintain MRI Operation certification; however, if the MR Operator has not completed any on-site scans in a 12-month period, re-evaluation may be required. Records of completion of training shall be retained per Section 4.3.8 below.

4.3. MRI Environment and Risks

Zones III and IV are considered the MRI environment. Access to the MRI environment is controlled via an electronic key card. The establishment of thorough and effective screening procedures for patients/subjects and other individuals is one of the **most critical** components of the CoNECT to guard the safety of all those preparing to undergo MRI procedures or to enter the MRI environment. An important aspect of protecting individuals from MRI system-related accidents and injuries involves an understanding of the risks associated with the various implants, devices, and accessories which may be present within or adjacent to the individual. Risks of other objects that may cause problems in this setting must also be evaluated. This requires obtaining information and documentation about these objects in order to provide the safest MRI environment possible. In addition, because many MR-related incidents have been due to deficiencies in screening methods and/or lack of proper control of access to the MRI environment, (especially with regard to preventing personal items and other potentially problematic objects from entering the MRI room) it is crucial to establish procedures and guidelines to help prevent such incidents from occurring.

The risks of MRI scanning can be classified into the following categories outlined below.

4.3.1. Acoustic Noise

The acoustic noise associated with MRI imaging is related to the mechanical movement of the gradient coils during the scanning process.

FDA Guidelines: "The acoustic noise levels associated with the device must be shown to be below the level of concern established by pertinent Federal Regulatory or other recognized standards setting organizations. If the acoustic noise is not below the level of concern, the sponsor must recommend steps to reduce or alleviate the noise perceived by the human subject." Current FDA guidelines follow the regulations of the International Electrotechnical Commission (IEC) Standard 601-2-33, which stipulate that for MR equipment used in medicine, hearing protection is required when the system can produce acoustic sound levels above 99 decibels (dB) and that the protection should be able to reduce noise levels to below 99 dB.

The FDA has approved systems for which noise levels have been quantified, ranging up to 105 dB RMS for scanners operating at field strengths of 1.5 Tesla. It is important to note that the static magnetic field strength is only one factor, and not necessarily the most important one, in determining acoustic noise. Among the factors listed above, the design and construction of the gradient coils plays a major role in the noise level that MRI scanning produces. Therefore, noise levels are not necessarily greater when scanning at 3.0 T compared with 1.5 T field strengths. It is nevertheless possible that, in some circumstances, our system could produce noise levels higher than 99 dB, as do many clinical systems operating at lower field strengths.

The acoustic noise levels perceived by human subjects when undergoing MRI examination in our 3.0 Tesla magnet constitutes a non-significant risk; specifically, our system will not be operated in a way that will present more noise to human subjects than is approved or recommended by the FDA.

Ensuring safety from Acoustic Noise as suggested by the FDA, we will take steps to reduce or alleviate the noise levels experienced by human subjects in this protocol. This will be accomplished by one of two methods:

- Use of disposable earplugs
- Use of acoustically-shielded headsets

4.3.2. Peripheral Nerve Stimulation

The time-varying magnetic fields used in MRI can, in some instances, induce stimulation of peripheral nerves, thereby producing sensations such as 'twitching' or 'tingling'. In very rare instances, this nerve stimulation can be painful. Nerve stimulation is particularly likely when human subjects are physically positioned in a way that increases the likelihood of inducing stimulation, such as with hands clasped, arms folded, or legs crossed. It should be noted that the parameter of interest here, dB/dt (the rate of change in the magnetic field per unit time), is not a function of the strength of the static magnetic field, so evaluating risk in a 3T MRI scanner involves the same considerations as evaluating other MRI systems operating at lower magnetic field strengths (i.e., the same issues apply to all the commercially available, FDA approved scanning systems). Thus, it is the gradient system only that needs to be evaluated to determine the risk of producing nerve stimulation.

FDA Guidelines: The FDA Guidance of 1995 was developed specifically to consider the fact that many clinical systems were capable of exceeding levels of dB/dt that could produce nerve stimulation. It was originally considered that a warning level should be implemented to guard against peripheral nerve stimulation, but the FDA finally concluded that: '... this warning level is not considered critical since there are no harmful effects associated with mild peripheral nerve stimulation'. The current guidelines therefore include monitoring procedures to help avoid painful peripheral nerve stimulation, and without specific dB/dt limitations.

The gradients used in our 3.0 Tesla MRI system will typically be operated at levels below those considered to be negligible according to FDA guidelines. Our system, like most commercially available, FDA-approved systems, does have the capacity to exceed this level, but it will include the same safeguards that are included in other FDA-approved clinical systems. In all circumstances, the system shall be operated in a way that minimize risk to the patient/subject.

Ensuring Safety from Peripheral Nerve Stimulation:

- All consent forms for studies that might induce peripheral nerve stimulation will provide this information.
- If the built-in stimulation monitor is bypassed by a user sequence, record of dB/dt value will also be included with the imaging data to help in an analysis of levels of peripheral nerve stimulation possibly perceived by human subjects.

- If the built-in stimulation monitor is bypassed by a user sequence, detailed calculations of the changes in magnetic field over time of which the gradient system is capable will be calculated, and conservative values will be selected as limits that will be used to determine when special additional monitoring is indicated. In these cases, monitoring procedures recommended by the FDA will be used.
- The gradient switching times and strengths will be monitored together with the routine assessment of all electrical components of the system.
- All MR Operators will receive special training on peripheral nerve stimulation in MRI.
- Before any scanning procedure that might stimulate peripheral nerves, an operator will:
 - Inform the human subject that peripheral nerve stimulation may occur
 - Describe the nature of the sensation to the human subject
 - Instruct human subjects not to clasp their hands, since this may create a conductive loop which will increase the possibility of stimulation
 - Maintain constant verbal contact with the human subject
 - Instruct human subjects to inform the MR operator if they experience discomfort or pain
 - Terminate the scan if the human subject complains of discomfort or pain
 - Complete a report of any incidents involving severe discomfort or pain, including a description of the associated circumstances (imaging parameters, dB/dt value, level of pain, etc.), and submit this report immediately both to the IRB and to the MR Director/MR Safety Officer

4.3.3. Tissue Heating

MRI scanning induces some heating of body tissues. This specific absorption rate (SAR) that determines heating is the amount of radiofrequency (RF) energy deposited (typically by a coil or “helmet”-like apparatus placed over the patient/subject’s head) per unit volume of tissue per unit time. RF energy in MRI examinations is not a function of the strength of the static magnetic field. Rather, the Specific Absorption Rate (SAR) for RF radiation is related to the amplitude of RF power, the duration of the RF pulse, the type of RF coil used, the frequency of RF radiation, the resistivity of the tissue, the configuration of the anatomical region being examined, and several other parameters.

FDA Guidelines: "The following are levels of concern at which the reviewer shall exercise appropriate actions to ensure that the safety of the device is substantially equivalent to a predicate device: A) If SAR 0.4 watts per kilogram (W/kg) whole body; and if SAR 8.0 W/kg spatial peak in any 1 gram of tissue; and if SAR 3.2 W/kg averaged over the head: below level of concern. Or B) If exposure to radiofrequency magnetic fields is insufficient to produce a core temperature increase in excess of 1°C and localized heating to greater than 38°C in the head, 39°C in the trunk and 40°C in the extremities: below level of concern. The parameter SAR cited above must be shown to fall below either of the two levels of concern by presentation of valid scientific measurement or calculation evidence sufficient to demonstrate that SAR is of no concern."

It should be noted that this guideline is based on the calculation of a system that has no thermoregulatory response, and thus it is a very conservative estimate compared with the temperature change that would be experienced in any living human subject. Normal diurnal temperature variations in humans, for example, are about +/-1°C from the normal set point 37°C, and healthy people with normal thermoregulatory responses can easily dissipate any excess (or, this instance, deposited) heat by increasing their peripheral blood flow or sweat rate. Thus, the heating effect of MRI with the SARs used in accord with these guidelines is extraordinarily unlikely to cause any acute effects in healthy human subjects.

Because all experiments performed on the 3.0 Tesla system will comply with FDA guidelines with regard to SAR, and because appropriate RF power safety checks are in place, the criterion for classification of NSR is satisfied.

Ensuring Safety from Tissue Heating Risks: The magnitude of temperature increase during MRI scanning is minimal. Increases are always within FDA guidelines, which include core temperature increases less than 1°C, as well as localized heating to less than 38°C in the head, 39°C in the trunk, and 40 °C in the extremities. Our 3.0 Tesla system has in place a means to monitor RF power levels and ensure that energy deposition is sufficiently low to stay well within these guidelines for temperature increases. First, a "system security" unit is employed to integrate the output of the RF amplifiers. This integration considers the amplitudes and duty cycle of the transmitter. If system security detects an output that might exceed the guidelines noted above, it automatically shuts down the entire RF power system. Secondly, all pulse sequences are evaluated, based on calculations and sound scientific measurements, to ensure that SAR remains within FDA-approved guidelines, prior to their use in humans. Any experiment performed on our 3.0 Tesla system will comply with all FDA guidelines with regard to RF power deposition. Proper and routine monitoring

of all RF electronics (e.g., coils, transmitters, system security, etc.) will be performed on a regular basis. All pulse sequences will be evaluated (by calculation and by valid scientific measurement) prior to use in humans.

4.3.4. Metallic Object Heating

Metallic objects inside the MRI can heat up during scanning procedures similarly to body tissues. Safeguards are in place to properly screen for these prior to entry; however, many clothing items contain metals within their fabric. Some of these are more obvious than others, zippers and bra wires for instance, but some are not so obvious such as metallic microfibers. Several patients across the United States have reported second-degree burns while wearing clothes containing such microfibers. While the WSU CoNNECT clothing policy (Section 4.4.10) does not require individuals undergoing an MRI to change into a gown, the risks of burns related to clothing items, specifically microfibers, should be explained in detail at the time of consent. This policy does, however, restrict specific clothing items and those restrictions shall be discussed at the time of consent.

4.3.5. Static Magnetic Fields

The possible risks of static magnetic fields have received much attention in the lay press, but scientific consensus on these risks has yet to be fully reached. The FDA has deemed that systems operating at 8.0 Tesla or less do not pose a significant risk. Moreover, experience with thousands of clinical studies over the past decade, and with multiple human investigations carried out at higher field strengths over this period, have not revealed risks of exposure to higher static magnetic fields. The most significant risk associated with static magnetic fields is that ferromagnetic objects, such as aneurysm clips or heart valves, can interact with the magnetic field of an MRI scanner, causing the device to malfunction or to move, and injuring the human subject. For some human subjects, rapid head movement while in the magnetic field may cause dizziness, vertigo, or a metallic taste in their mouth.

FDA Guidelines: "Studies conducted at 8T or less are not considered significant risk" (FDA Center for Devices and Radiological Health, memorandum 7-14-03).

This category of risk applies to work conducted around superconducting magnets of any kind (including standard clinical diagnostic MRI units). It is not unique to our 3.0 Tesla facility. The MRI facility will maintain a safety policy to safeguard human subjects and staff members from these incidental risks. Systems with static magnetic field less than 8 Tesla have been considered to represent a non-significant risk (NSR) by the FDA. The static magnetic field of our system (3.0 Tesla) is therefore to be classified as posing NSR to human subjects.

Ensuring Safety from Static Magnetic Field Risks: The minimization of risks associated with the static magnetic field of 3.0 Tesla is mainly related to incidental risks (see below). These risks are the same as in other commercially available clinical systems, and like other clinical MRI centers, our facility will incorporate a complete range of procedures, including:

- All MR Research Users will assure the security of the restricted access area. Entrance doors to the MRI suite (Zones III and IV) will be kept closed at all times. Access to the MRI suite will be tightly controlled, allowing access for only personnel and human subjects who have legitimate reason to be there. Doors to the MRI suite will be securely locked when not in use.
- Entry-ways to the MRI suite will be labeled with clear visible signs warning of the presence of the magnetic field and the exclusion from entry by individuals with implanted metal objects such as prostheses, pins, clips, IUD's, pacemakers, etc.
- The MR Operator or Level 2 MR Personnel will conduct careful screening of individuals before they enter the magnet room (Appendices 1-3).
- To minimize the potential for dizziness or a metallic taste, it is recommended that the human subject remain still while in the region of high static magnetic field.

4.3.6. Pregnancy

The effects MRI has on a fetus (unborn baby) are unknown. The concern of MRI on a fetus mainly arise from potential harmful effects from the tissue heating which can occur during normal MRI scanning. Therefore, female patients/subjects that are pregnant are not eligible to participate in an MRI scan at the CoNNECT. An over-the-counter (OTC) or laboratory urine dipstick pregnancy test **MUST** be completed prior to undergoing any MRI procedures to detect the presence of human chorionic gonadotropin (hCG), hormones produced by cells formed in the placenta and an indicator of pregnancy. OTC tests must be shown in clinical tests to have a sensitivity for hCG at or below 25 milli-international units/milliliter (mIU/mL), capable of detecting >80% of pregnancies on the day of the missed period. If

the subject/patient returns for subsequent research MRI scans, a pregnancy test will not be required so long as the MRIs are within a week (7 days) of the administered pregnancy test.

The following language can be used to describe the special risks to pregnant women in the Risks section of your Protocol and Consent documents:

“The effects of MRI on a developing fetus are unknown. Therefore, pregnant women will be disqualified from participating in this study. Female volunteers will be given a urine pregnancy test as part of the medical screening process prior to each MRI procedure. Pregnancy tests will remain valid for 7 days, thus additional pregnancy tests will not be required for multiple MRIs performed within a 7-day period. Volunteers who test positive will not be allowed to participate. The physician in charge of eligibility decisions will be informed of the positive result and will be asked to contact the participant within 24 hours to follow up.”

4.3.7. Incidental Risks

The physical confinement and isolation produced by the scanner could cause mild to moderate emotional distress, although in our extensive past experience, human subjects generally tolerated the procedures remarkably well.

All human subjects will be able to communicate directly with the operators to inform them of any emotional or physical distress during the scanning procedure. If they wish, the scan will be terminated immediately and the human subject will be removed from the scanner.

4.3.8. Ensuring Document Safety

Records regarding MRI safety and compliance, human subjects, scans, equipment maintenance and repair, as well as usage, are maintained by the CoNNECT staff and PI overseeing the research study. A list of records is outlined below:

Training Records: maintains safety and compliance training records for all personnel. The MR Director manages these records and maintains documentation of proficiency testing and copies of certification for MR Operators.

Patient/Subject Screening Forms: Preliminary safety screening forms for human subjects are kept on file by the PI overseeing each study and a copy must be provided to the WSU CoNNECT. These forms were developed to be completed without containing any protected health information. It is the responsibility of the MR Research Users to bring the patient/subject’s screening form to each MRI scan.

Urine Dipstick Pregnancy Results: The PI overseeing each study must document urine dipstick pregnancy test results for each study in accordance with the WSU CoNNECT policy outlined in this manual. The documented results should be made available for the MR Operator’s review at EVERY MRI scan.

MR Research User Screening Forms: The MR Director maintains safety screening forms for MR Research Users and visitors who enter the scanner room. These forms are maintained for a period of 1 year in a locking file cabinet.

Consent Forms: Signed consent forms for each human subject involved in a study are maintained by the PI in accordance with IRB requirements.

Data: The naming convention for all research studies will not contain any identifying information and will be listed as IRB protocol number and unique subject identifier separated by a space. For example:

67108 101

where 67108 is the IRB protocol number and 101 is the unique subject identifier.

Each subject will be prescribed with the birthdate of Jan 1, 1960.

The Registration ID will be the IRB protocol number followed by the unique subject identifier without any spaces.

Per the rules and regulations of the WSU IRB, it is the jurisdiction and responsibility of the PI to keep their human subject volunteer information protected and confidential. They will retain copies of their own volunteer’s signed informed consents and assents, MRI screening forms, and any other documentation related to participation in their study. Once imaging data has been shared with the PI, it becomes their responsibility to maintain and use the data in a confidential and appropriate manner. The WSU CoNNECT will maintain de-identified copies of the MRI screening forms for its own assurances.

Data Logs: The following logs are kept by the MR Director, MR Operator, and MR Scientist:

- Quality assurance data.
- Weekly temperature and humidity readings for the scanner and equipment rooms.
- Weekly cryogen readings.
- Scanner and equipment room filter change dates.
- Scanner communication log with the MRI manufacturer for maintenance and scanner errors.
- IP addresses, port numbers, application entry titles.
- Usage log of all MRI scans.

Usage Logs: Accurate records regarding use of the scanner are required for proper billing and reporting to federal funding agencies. These records are reviewed and maintained by the CoNNECT staff but managed by the MR Director. When using the scanner, MR Operators must record at least the following information:

- Date.
- IRB number (if applicable)
- PI or faculty/staff/affiliate
- Type of project or study (pilot study, human subject, phantom scanning, validation testing, etc.).
- Human subject number (when appropriate).
- Start and end time of scanner use.

4.3.9. Equipment Screening

Any additional equipment to be used that is not currently in use within the magnet room must be approved by the WSU CoNNECT MR Scientist or MR Safety Officer. MR Research Users are cautioned to NEVER take equipment into the magnet room without prior testing for magnetic attraction. MR Research Users are cautioned to NEVER implement the use of equipment with patient/subject before testing with a phantom or other method that will not potentially cause harm to a patient/subject or to related equipment. Equipment operating within the magnetic environment must be monitored for any spurious signals that may cause artifacts on images or acquired data.

MRI safe equipment is developed for specific magnetic field strengths and MRI system configurations. Equipment that may operate safely within a magnet room is NOT necessarily safe to operate in another magnet room even if the magnets are the same static field strength. Routine inspection and maintenance of equipment must be performed. Broken or malfunctioning equipment must be identified and reported to the MR Director.

4.3.10. Incidental Findings

Incidental findings are a potential risk associated with MRI, and if an incidental finding is observed the patient/subject may experience an increased emotional response and anxiety. The WSU CoNNECT incidental findings policy can be found in Section 4.5.

4.4. MRI Safety Screening & Patient/Subject Entry Protocol

The following sections outline the general procedure for entry into Zones III and IV. It is critical that patients/visitors are screened prior to arriving at the MRI to reduce the risk of non-compliance with the following standards of practice.

4.4.1. Exclusion of Individuals

Specific exclusion criteria must be evaluated prior to scheduling any MRI at the CoNNECT. Individuals and patients/subjects with cardiac pacemakers, implanted neural stimulators, or with attached or implanted electronic devices (e.g., insulin pumps), with brain aneurysm clips, are specifically excluded from having MRI scans at the CoNNECT. All patients/subjects that have other types of implanted devices must have unanimous approval by the MR Safety Officer, MR Scientist, MR Director, or MR Medical Director. The PI or MR Research User must notify one or more of these individuals of a patient/subject's implanted device prior to scheduling for further evaluation of compatibility to be scanned.

4.4.2. Pre-Entry Screening

All individuals, including MR Research Users, employees and students, who work within the magnetic environment, must be screened prior to entry into Zone III. Standardized screening forms for patients/subjects and MR Research Users/visitors are available at wright.edu/neuroimaging (Appendices 1 and 2). Only these forms are acceptable methods for pre-entry screening. These forms must be signed by an individual with Level 2 MR Personnel status prior to entry into Zone III. Screening forms are valid for 1 year.

4.4.3. Pregnancy

Individuals who are or may be pregnant are not allowed to remain in the MR scanner room while the RF and gradients are operating. Pregnant individuals may remain in the control room and enter the magnet room between scans during the study. This includes staff or individuals accompanying the subject/patient.

Female patients/subjects that are pregnant are not eligible to participate in an MRI scan at the CoNNECT. An OTC or laboratory pregnancy test **MUST** be completed prior to undergoing any MRI procedures. If the subject/patient returns for subsequent research MRI scans, a pregnancy test will not be required so long as the MRIs are within a week of the administered pregnancy test.

The following language can be used in the Procedures description of the Consent document:

If you are a woman of reproductive age and are able to get pregnant (i.e., not post-menopausal, have not had a hysterectomy, and do not have a physical condition that prevents you from becoming pregnant), you will be required to take a urine dipstick pregnancy test prior to any MRI procedures to confirm you are not pregnant. This is to ensure the safety of the procedures. If you are found to be pregnant or refuse the test, you will not be allowed to continue in the study. Pregnancy tests will be repeated if not completed within the 7 days prior to your schedule MRI.

The following language can be used in the Required Equipment section of your Protocol document:

Urine pregnancy test: Female volunteers will be administered a pregnancy test within 7 days of each visit to check for the presence of the hormone hCG in their urine.

The following language can be used to describe data collection procedures in the Protocol document:

All female participants will be required to take a urine dipstick pregnancy test confirming they are not pregnant. If a subject is found to be pregnant or refuses to take the pregnancy test, she will not be allowed to continue in the study.

4.4.4. Implants and Devices

Implants and devices are evolving rapidly and must be thoroughly investigated if potential patients/subjects or individuals who will enter the magnetic environment indicate their presence. Implants that are approved to scan at 1.5T are not necessarily safe to scan at 3T. Before scheduling a patient/subject that has an implanted device, both the PI and the MR Safety Officer must be notified to confirm compatibility of the implanted device with the magnetic field strength that will be used to perform the MR scan. If the individual knows or has documentation as to the specific manufacturer and type of device, then the following steps are implemented:

- Look up the item by the manufacturer in the current Reference Manual for Magnetic Resonance Safety, Implants, and Devices by Frank G. Shellock, Ph.D. or on the web site: <http://www.mrisafety.com>
- If the device or object is not listed there or has not been tested at 3 Tesla, then contact the manufacturer for the following information and written documentation:
 - Have the manufacturer email or fax the text that states the device is MRI safe and at which magnetic field strength(s), and conditions, it is safe.
 - The text sent should include the FDA date stamp that verifies the device is MRI safe at 3 Tesla or the specific conditions which must be adhered to for the field strength the individual will be entering.

The assurance of safety needs to be verified BEFORE the individual is brought to the facility so that the operator has adequate information to ensure the safety of the individual they are placing or leading into the magnetic environment. The device information should be provided in the MR safety screening form so there is documentation that the safety of the subject was investigated before the MRI study was performed.

4.4.5. Screening Patients and Individuals with Metallic Foreign Bodies

All patients/subjects and individuals with a history of being injured by a metallic foreign body such as a bullet, shrapnel, or other type of metallic object should be thoroughly screened and evaluated prior to admission to Zone IV. This is particularly important because serious injury may occur as a result of movement or dislodgment of the metallic foreign body as it is attracted by the magnetic field of the MR system. In addition, heating may occur, although this tends to only happen if the object forms a resonant conductive loop.

The relative risk of injury is dependent on the ferromagnetic properties of the foreign body, the geometry and dimensions of the object, the strength of the static magnetic field, and the strength of the spatial gradient of the MR system. Additionally, the potential for injury is related to the amount of force with which the object is fixed within the tissue (i.e., counter-force or retention force) and whether or not it is positioned in or adjacent to a particularly sensitive site of the body. These sensitive sites include vital neural, vascular, or soft tissue structures.

The use of plain film radiography is the technique of choice recommended to detect metallic foreign bodies for individuals and patients/subjects prior to admission to Zone IV. The WSU CoNNECT does not provide plain film radiography and, therefore, a patient/subject should not be admitted to the MR environment until they have had plain film radiography documenting that there is not any potential danger to the individual. This includes screening individuals and patients/subjects for the presence of metallic orbital foreign bodies. The inherent sensitivity of plain film radiography is considered to be sufficient to identify any metal with a mass large enough to present a hazard to patients/subjects in the MR environment.

4.4.6. Orbital Foreign Body Screening Guidelines

The procedure to follow with regard to an individual or patients/subject suspected of having an orbital foreign body involves a clinical screening protocol that entails asking the individual if they have had an eye injury. If an eye injury from a metallic object was sustained, the individual is asked if they have had an MRI scan that was cleared by conventional radiography (x-rays) after the eye injury. If they indicate that they have had an MRI scan after the eye injury that has been cleared of metallic objects by x-rays, then MRI procedures can proceed. If the individual has had an ocular injury, but has not been cleared of metallic objects sustained to the eyes, then they must have x-rays to confirm that there are not any metallic objects in the eyes. The MRI scan must be postponed until documentation has been received indicating that there are not any metallic objects in the eyes.

4.4.7. Claustrophobia Screening

About 10% to 20% of the general population has claustrophobic tendencies. In many cases patients/subjects who think they are claustrophobic are able to go through an MRI study with some reassurance. MR Research Users should screen for claustrophobia prior to scheduling an MRI at the WSU CoNNECT.

4.4.8. Medical Status Screening

Patients/Subjects must be evaluated for medical status or issues that may prevent them from lying flat or holding still for long periods of time. Patients/subjects who are dependent on continuous medication via external or internal devices should be excluded from research MRI studies. Patients/Subjects who do not understand directions or cannot cooperate with the MR Research Users to ensure a successful study should be excluded. In addition, patients/subjects that are unable to ambulate on and off of the MRI table with minimal assistances may be excluded from an MR research study. Exceptions may be evaluated on a case by case basis depending on the purpose of the MRI study.

4.4.9. Metallic Screening

A metallic screening system (Ferroguard Screener, MetraSens, Chicago, IL) is installed in Zone III. All patients/subjects are required to be screened for metallic objects prior to entry to Zone IV. Patients/subjects will stand approximately 1 foot in front of the system and perform a complete 360-degree rotation (slowly). If the system indicates the potential for metal, the MR Operator will perform a thorough verbal check with the patient/subject to ensure pockets are clear of any objects, all jewelry and watches are removed, and any piercings have been removed. If the patient/subject is female, the MR Operator will verbally confirm a bra, if present, does not have an underwire. This system is quite sensitive and if any additional objects are removed from the patient, the screening will be repeated. If not, continuing is at the discretion of the MR Operator.

4.4.10. Required Dress for Entry

MR Research Users and visitors are allowed to wear normal clothes within and throughout Zones III and IV. However, individuals should be particularly aware of any hair pins/clips and tie clips or any other metallic items that are not secured to a person.

Patients/subjects or any individual undergoing MRI procedures are NOT allowed to wear normal clothes during the procedures. Those undergoing MRI procedures must:

- Remove all metallic objects including piercings, jewelry, watches, etc.
- Remove any clothing items that contain metal such as zippers, metal buttons, or bras with underwires

- Females are encouraged to wear sports bras, specifically wireless bras

Individuals undergoing MRI procedures are encouraged to wear gym cloths consisting of sweat pants or gym shorts and plain t-shirts not containing logos or writing/graphics. Gowns and/or approved dress items will be available for any patient/subject who does not have proper clothing items. Any person refusing to remove any items of concern will not be able to undergo MRI procedures. The decision to allow clothing items or discontinue an MRI procedure will purely be at the discretion of the MR Operator; however, the MR Operator is encouraged to reach out to the MR Safety Officer, MR Scientist, or MR Director with any clothing issues.

4.5. Incidental Findings

Variations from expected brain morphology can be seen in patients/subjects undergoing MRI scans. Variations in brain morphology may or may not have medical implications.

The CoNNECT is a non-medical facility and has established the following policy for structural MRI scans obtained for research purposes:

- All human research MRI protocols undertaken at the CoNNECT shall include in the IRB application an explicit description of the procedure for handling all findings, including incidental findings.
- Incidental findings are reportable events and must be reported to the appropriate IRB within the required period of realization set forth by the IRB of record. WSU IRB requires incidental findings to be reported within **10** days of realization.
- The informed consent document shall contain an explicit description of the limits of communication between the study staff and the subject with respect to scan findings.
- All subjects have the right to be informed of the strengths and limitations of the research team in identifying, interpreting, or communicating findings.

The incidental finding policy should be included in the Consent Form (a sample is provided in Section 4.5.5). The consent form shall include a designation of the individual who should be notified of any incidental findings, If this information is not provided, notification shall be mailed to the subject in writing.

4.5.1. T1 and T2 FLAIR Imaging

In recognition of the fact that, on occasion, incidental findings may need to be investigated medically, and in a good-faith effort to inform research subjects of that possibility, the policy of the CoNNECT is to collect, at minimum, a standardized T1 and T2 FLAIR (excluded if a better-quality scan is included in the research protocol) for each patient/subject. For studies involving patients/subjects without any known brain damage, a DVD copy of the structural data (T1 and T2 FLAIR) obtained during the study will be provided upon request. \

4.5.2. Abnormalities identified by MR Operator

If the MR Operator documents any abnormalities, they will request a review by the MR Director, and/or MR Medical Director. This review will occur within 4 weeks of the scan date. However, in the event of an emergent case where a midline shift or enlarged ventricles (i.e., hydrocephalus) is/are noted by the MR Operator, the MR Operator will contact the study principal investigator immediately to determine the appropriate course of action. The MR Operator will also contact the MR Director or MR Medical Director and an emergency evaluation will be performed within 12 hours, if not immediately.

If any patient/subject has multiple MRIs within a 9-week period, these scans and the review procedure may be waived.

4.5.3. Routine Review

All T1 and T2 FLAIR scans will be provided to the MR Scientist, MR Director, and/or MR Medical Director by the MR Operator without identifying data for a secondary review. Scans will solely contain the CoNNECT identifying number and gender of the subject. In the unlikely event that the team identifies an incidental finding, the secondary reviewer will inform the MR Research User that an incidental finding was determined and the subject may not be appropriate for research. The MR Research User shall follow their documented IRB-approved plan for incidental findings.

There are two exceptions to the policy of routinely reviewing all T1 and T2 Flair scans:

1. Subjects who are part of repeated scanning for multiple studies, may only have their scans reviewed after one MRI session. If their participation continues for over six months, the first scan performed 6 months after the previously reviewed scan may be sent for review. We need your cooperation in identifying such subjects.

2. Subjects with known brain diseases who are part of structural/functional MR protocols will not have their scans sent to MR Director and/or MR Medical Director for review.

Investigators who will use brain damaged subjects in research protocols should follow the policy of providing the structural (T1 and T2 FLAIR) scan to the patients/subjects. CDs with the structural images are offered to the patients/subjects so that those who wish can consult directly with their own medical practitioner.

4.5.4. Suggested Language for Informed Consents

All investigators conducting human subjects research who plan to use the CoNNECT must obtain IRB approval for their research protocol. Under no circumstances will such an investigator be allowed to use the facility without submitting proof of IRB approval. The following language should be used in every IRB protocol:

“The magnetic resonance imaging (MRI) scan you will receive during the course of this study is strictly for research purposes . It is not a clinical scan intended for diagnostic or therapeutic purposes and there is no physician-patient relationship being established in relation to the MRI scanning that is being performed. The Center of Neuroimaging and Neuro-Evaluation of Cognitive Technologies is a research center. It is NOT a Clinical MRI facility. Therefore, the staff are unable to make any medical comments about your scan. Do not ask them whether your scan is normal or abnormal as they are not able to tell you. However, any structural scans obtained in normal research subjects are reviewed by the MR Operator and may receive a second review from a doctor (PhD or MD). In the rare event the doctor detects an abnormality (about 1 to 5 in 1000 healthy people), you or your designee will be notified that an abnormality was detected and you will be offered a disk containing the structural images. You will need to consult with a physician of your choosing for clinical diagnosis, care or treatment. .”

4.5.5. Suggested Language for Informing Patients/Subjects of an Incidental Finding

Informing a patient/subject of a suspected incidental finding can present undue stress and should be handled delicately by the MR Researchers. The language provided is to be used as a template:

“The scans we acquired as part of your participation in the MRI study are not intended for diagnosis and our facility is not a clinical MRI facility. However, we did observe findings in your images that may or may not be clinically significant. We are providing you with a disc containing some of your MRI images. You will need to have them reviewed by your personal physician to determine any medical or clinical significance.”

4.6. Locking Procedures

Access to Zones III and IV must be controlled at all times. Therefore, it is critical to keep the entry into Zone III (NEC 137B) closed at all times. The entry into Zone IV (NEC 137BA) shall remain closed at all times. This entry can remain open while a MR Research User or MR Operator are inside Zone IV and the MRI is not in operation. The entry into Zone IV shall remain locked at all times when a Level 2 MR Personnel is not present in Zone III. Only temporary circumstances approved by the MR Director, MR Medical Director or MR Scientist shall deviate from this policy.

4.7. Gadolinium-Based Contrast Agents

The U.S. FDA approved gadolinium-based contrast agents (GBCAs) for diagnosis and treatment guidance to increase the conspicuity of diseased tissues. According to the ACR guidance on gadolinium contrast agents, radiologists since 2006 have withheld GBCA use in patients with acute kidney injury and/or severe chronic kidney disease because of increased risk of nephrogenic systemic fibrosis (NSF). More recently, ACR states that residual traces of gadolinium were found within brain tissue of people who received multiple doses of GBCAs. These depositions of gadolinium appeared in specific areas of the brain even in the absence of disease and with an intact blood brain barrier. In July 2015, the FDA published a Safety Alert indicating an investigation into the risk and clinical significance of gadolinium deposits.

Despite the lack of adverse health effects uncovered in the FDA’s investigation, the use of GBCAs in the WSU CoCONNECT is *NOT* authorized due to the increased risk, additional medical evaluations, adverse reactions, GBCA selection requirements, and monitoring requirements.

5. Emergency Safety Procedures

5.1.1. General Procedure

Wright State’s MRI scanner has been approved by the Food and Drug Administration (FDA) for human and animal use. It will be used solely for research purposes that will involve the use of human subjects, as well as MRI phantoms (containers filled with gelatinous materials or chemicals). The MRI may be used outside of its FDA-approved limits due to the research designation.

5.1.2. Emergency Shutdown

The Emergency SHUTDOWN procedure for the Philips dStream Achieva 3.0T can be executed using the procedures identified below. These steps must be executed in the proper order identified herein. Each MR Operator will be trained regarding the location and procedure for emergency SHUTDOWN procedure. Conducting the Emergency SHUTDOWN procedure turns off the entire MR system EXCEPT for the static magnetic field and the MAGNET RUNDOWN unit (described below). Pushing the Emergency SHUTDOWN DOES NOT PRODUCE A QUENCH. It does not turn off the lights. Also, power to the stimulation equipment will not be interrupted, so be aware that electrical or fire hazards may still be present. The button should be used ONLY TO STOP A SCAN DURING A HUMAN SUBJECT EMERGENCY or DURING A SERIOUS EQUIPMENT FAULT OR HAZARD, such as fire or water in the vicinity of the MR equipment.

- Shutdown the operator’s console
- Locate the gMDU in the MR equipment room (Figure 2).
- Set the following switches to OFF in the following order:
 1. F6
 2. Q1
 3. Q4
 4. F7
 5. F8
 6. Q2
 7. QT



Figure 3. Philips dStream Achieva 3.0T gMDU located in the MRI Equipment Room (Zone III).

The Philips dStream Achieva 3.0T may be turned back on after at least waiting 1 minute following an Emergency SHUTDOWN using the following steps in order:

- Set the following switches to ON with a 5 second delay between steps:
 1. QT
 2. Q2
 3. Q1
 4. F7
 5. F8
 6. Q4
 7. F6
- The host computer may need turn on or may need turned on by pressing the power button on the system in the server rack in the MR equipment room

5.1.3. Emergency Quench

The MRI magnet is maintained at a high field strength by means of super-cooling its conductive loops of wire with liquid helium, which is at an extremely low temperature – close to absolute zero (about 4°K). In certain circumstances, this helium may be rapidly vented off, warming the magnet and causing it to quickly lose its magnetic field either intentionally or unintentionally. This is known as a “quench.” A quench may be released by pressing the magnet’s “Emergency RUNDOWN” switch (Figure 4; the one with a yellow “emergency magnet off” label). This is referred to a “controlled quench”. Another source for quenching is a helium fill level that decreases to a point (about 30%) where the magnet begins to warm up. This is known as an “uncontrolled quench”. In rare instances, a spontaneous quench may be observed that cannot be explained by the presence of obvious external sources.



Figure 4. The WSU CoNNECT is fitted with two Emergency RUNDOWN switches. One is located near the control station (Zone III) and the other is in the MRI room (Zone IV).

Intentional or Controlled Quench

A controlled quench should only be initiated by authorized personnel in the event of a potentially life-threatening emergency, such as an individual in respiratory distress being pinned to the magnet by a metallic object. A quench of the magnet is extremely expensive and has the potential to damage the equipment. An intentional quench is performed in an extreme emergency to rapidly run the magnetic field to zero. A quench of the magnet should only be performed when:

- a) A person is pinned to the magnet and is unable to free themselves without harm.
- b) There is a fire in the MRI scanner, equipment, or console room.
- c) There is a fire in another area that is a threat to the MRI Suite

In non-life threatening situations, such as a piece of equipment being pinned against the magnet, no one should initiate a quench. If a metal object traps a human subject in the magnet bore so that removal is not possible without quenching the magnet, or if it is determined that a potentially life-threatening situation exists, the operator or his designee should press one of the two Magnet Rundown buttons.

- a) The magnetic field will dissipate in approximately one minute.
- b) Use the intercom to alert the human subject to stay calm and remain on the table until the operator gains access to the room to offer assistance.
- c) If the quench was initiated because of a medical emergency, the procedures listed above under Medical Emergencies should be followed.
- d) After ensuring that the magnet and equipment rooms are secure and that all individual have exited these areas, inform the director and notify Philips of quench (see below).
- e) Secure magnet room door. The MRI magnet operator is responsible to ensure no one enters the magnet room without proper screening for MRI safety. Note that even in the event of a quench, a significant magnetic field may remain for some period of time.
- f) After a quench, the usual service procedure goes into effect (please refer to the Philips System Manual located in the cabinet in the control room). Philips Customer service has to be notified as quickly as possible to put the system back into operation.
- g) File an incident report and notify appropriate University personnel. The following should be notified:
 - i. WSU Dayton Campus Public Safety.
 - ii. WSU Department of Environmental Health and Safety
 - iii. MR Medical Director/MR Safety Officer

Uncontrolled Quench (or spontaneous quench)

It is possible, but highly unlikely, that a spontaneous quench of a magnet could be caused by an accident (earthquake, fire, etc.). If a spontaneous quench occurs, remove the human subject immediately, following the same procedure as a user-induced quench.

5.1.4. Emergency Magnet Rundown

The device for an Emergency Rundown allows for the rapid reduction of the magnetic field in about two minutes. It will also boil-off cryogenics and therefore, unlike the Emergency SHUTDOWN button, this button WILL PRODUCE A QUENCH. The button is located inside the magnet room on the left wall adjacent to the door. Only the MRI Scientist or MR Director is authorized to trigger the rundown UNLESS A HUMAN LIFE IS AT RISK (i.e. do not quench the magnet if a piece of furniture or equipment got into the bore. Such objects can be safely removed by calling a Philips' service engineer who will slowly power down the magnet). The rundown should be triggered to free someone pinned to the magnet, or to remove a large ferromagnetic object captured in the magnetic field when injury to the human subject is imminent.

5.1.5. Power Failure

In the event of a power failure, if an MRI study is in progress, the human subject will first be removed from the bore manually. Simply pull the patient table out of the bore. Once human subject safety is secured, the MR Operator will return to the MRI suite and properly shutdown all of the computers (which should be receiving power from UPS), thus preventing corruption of the software on the MRI scanner. The WSU CoCONNECT and ancillary systems will remain off until facilities notifies the MR Director of adequate power return.

5.1.6. Medical Emergency

Medical emergencies during MRI scanning are an unlikely event; however, the following has been developed in the event a medical emergency occurs during scanning.

- In case of emergency, the MR Operator will dial 2111 or 911, or instruct an assistant to, to report the nature of the emergency along with the location to the response team.
- Emergency procedures shall NOT be administered in the magnet room (Zone IV), and NO medical equipment shall be allowed in the magnet room (Zone IV). Instead, the MR Operator or emergency team shall remove the human subject immediately from the magnet room (Zone IV) and transport her/him Zone III or Zone II, where the emergency will be handled by emergency responders.
- The magnet room (Zone IV) door shall be closed upon removal of the human subject to avoid entry of any metallic objects.
- If not already onsite, the principal investigator shall be contacted and informed of the nature of the emergency.
- All adverse events shall be documented on an incident report. The IRB and the MR Medical Director/MR Safety Officer will be notified immediately via telephone and within 48 hours in writing.
- If the medical emergency was caused by an equipment malfunction, any research utilizing the system will be halted until the malfunction is rectified.

5.1.7. Fire Emergency

- Internal extension 2111 or 911 shall be dialed identifying the type and location of fire.
- In the event of a fire in the building, the MR Operator shall immediately remove the human subject from the magnet room (Zone IV).
- If an electrical fire were to occur in the MRI Suite(s) (including control, magnet, or adjacent laboratory space Zones II, III and IV), one nonferrous water mist fire extinguisher is located within the control room (Zone III) to contain the fire. Personnel are not required to fight fires and should evacuate the building immediately in the event of a fire.
- All personnel should evacuate the building according to the building evacuation plan, in a calm manner. Never use elevators in the event of a fire emergency.
- If the MR Operator is able to disconnect electrical power to the MRI system safely they should do this by completing the emergency SHUTDOWN procedure.
- If the fire occurs in the magnet room (Zone IV), the fire shall be extinguished using a non-ferrous fire extinguisher (the fire extinguisher near the outside door of the control room (Zone III) is non-ferrous and is labeled MR Safe).
- If the fire is not extinguished after emptying the available extinguisher, or jeopardizes the safety of personnel, the magnetic field must be removed by pressing the MAGNET STOP button on the Emergency Rundown Unit.
- All personnel, including firefighters, must be screened for entry into magnet room until 2 minutes has passed since the quench.
- All doors in the MRI suite shall be closed to contain the fire.
- Do not reenter the building until granted permission by the Fire Department.

5.1.8. Weather Emergency

In the event of a weather emergency that has triggered a building alarm (i.e., tornado warning), scanning procedures should be halted immediately. The MR Operator shall remove the patient/subject from the scanner and all personnel should proceed to the nearest shelter location. All doors in the MR Suite (Zones III and IV) shall be closed upon exit. Scanning can resume once the emergency status has been lifted.

6. Ancillary Equipment

Ancillary equipment may be utilized in Zones II, III, or IV. The MR Scientist must approve any equipment for use in Zone IV prior entry into Zone IV. Any equipment other than MRI pads and coils shall be marked with MR Safe or MR Conditional stickers prior to entry into Zone IV. All MR Operators shall be trained in each equipment and its safe operating area within Zone IV. For instance, some equipment shall be deemed MR Conditional but only safe to operate

outside of the 100 Gauss field. The MR Scientist will review the safety of equipment in regards to heating and magnetic compatibility.

7. Housekeeping Policy

It is the policy of the WSU CoNNECT to leave the facility in the same condition as arrival. The following outline regular cleaning that should ensure the spirit of this policy.

7.1. Cleaning Per Scan

Cleaning of the MRI scanning room (Zone IV) shall be conducted after each MRI scan. This cleaning consists of:

- Placing all trash in the appropriate canister
- Picking up any linens and placing in the appropriate canister
- Wiping down the coil, table and pads
- Place pads in their appropriate storage location
- Disconnect head coil from the table to ensure coil does not overheat
- Raise table to utmost position to ensure proper ventilation

7.2. Daily Cleaning

Cleaning of Zones III and IV shall be conducted daily by MR Operators and/or MR Research Users. This may consist of a light sweep with a broom or duster, and ensuring the counters of the control room (Zone III) are clean and orderly. All trash shall be placed in canisters and full canisters shall be placed in the hallway outside of Zone II.

7.3. Weekly Cleaning

A deeper weekly cleaning shall be conducted by MR Operators and/or MR Research Users. This deeper cleaning shall include all daily cleaning activities in addition to mopping Zones III and IV and wiping down the countertops in Zones III and IV with Clorox wipes or another cleaning substance.

7.4. WSU Housekeeping

WSU housekeeping may perform regular cleaning inside the WSU CoNNECT. Housekeepers may clean Zones II and III but shall not enter Zone IV. The MR Director may modify this restriction under certain circumstances such as regular applications of floor wax; however, the MR Director must screen and supervise the housekeepers.

8. Maintenance and Facilities

8.1. Philips Service

Philips service technicians will likely be on site fairly regularly. Philips service technicians shall arrange visits with the MR Director or MR Scientist. They shall be provided access to the entire facility.

8.2. WSU Facility Operations

WSU facility operations staff may need to visit the site to perform maintenance activities. Entrance to Zone IV shall be treated as any other entrant with pre-screening using at least the MR Visitor MRI Screening Form (Appendix 3). They shall also be monitored carefully by the MR Scientist or MR Director to ensure no equipment which may pose a danger enters Zone IV.

9. Revocation

Safety is our number one priority and, as such, the right to revoke access to the MRI, user privileges, or personnel classifications (MR Operator, Level 1 MR Personnel, Level 2 MR Personnel. Revocation is anticipated to be a last resort and used very infrequently. Revocation is expected to be a consequence of repeated failures to follow the policies and procedures in this manual. A single failure which pose a major safety risk could result in immediate revocation. Revocation is solely the determination of the MR Medical Director or MR Director. A notice of revocation

must be provided in writing and must include the reason for revocation and the required items to complete for reinstatement.

Appendix 1 - Subject MRI Screening Form

WSU CoNNECT SUBJECT SCREENING FORM

I attest that the information provided is correct to the best of my knowledge. By completing, I acknowledge I have read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo. **I MUST NOTIFY A MEMBER OF THE STUDY OR FACILITY IMMEDIATELY IF THERE IS A CHANGE IN ANY ITEM COVERED ON THIS FORM.**

Date ____/____/____ Do you have corrective lenses? No Yes
 STUDY ID _____ If yes, please indicate your prescription:
 Age ____ yrs Weight ____ lbs Left _____
 Right eye (if different than left) _____

Male Female Body Part to be Examined _____
 IRB PROTOCOL # _____

Principal Investigator _____ PI Phone # (____) ____-____

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? No Yes
 2. Have you had a prior diagnostic imaging study or examination (MRI, CT, Ultrasound, X-ray, etc.)? No Yes
 If yes, please list: Body part _____
 MRI _____
 CT/CAT Scan _____
 X-Ray _____
 Ultrasound _____
 Nuclear Medicine _____
 Other _____
 3. Have you experienced any problem related to a previous MRI examination or MR procedure? No Yes
 If yes, please describe: _____
 4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)? No Yes
 If yes, please describe: _____
 5. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? No Yes
 If yes, please describe: _____
 6. Are you currently taking or have you recently taken any medication or drug? No Yes
 If yes, please list: _____
 7. Are you allergic to any medication? No Yes
 If yes, please list: _____
 8. Do you have a history of asthma, allergic reaction, respiratory disease, or reaction to a contrast medium or dye used for an MRI, CT, or X-ray examination? No Yes
 9. Do you have anemia or any disease(s) that affects your blood, a history of renal (kidney) disease, renal (kidney) failure, renal (kidney) transplant, high blood pressure (hypertension), liver (hepatic) disease, a history of diabetes, or seizures? No Yes
 If yes, please describe: _____
- For female patients:**
10. Date of last menstrual period: ____/____/____ Post menopausal? No Yes
 11. Are you pregnant or experiencing a late menstrual period? No Yes
 12. Are you taking oral contraceptives or receiving hormonal treatment? No Yes
 13. Are you taking any type of fertility medication or having fertility treatments? No Yes
 If yes, please describe: _____
 14. Are you currently breastfeeding? No Yes

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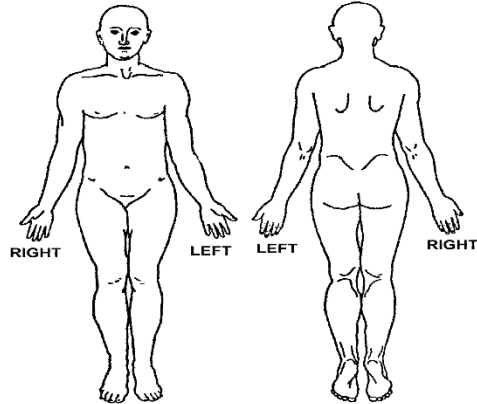


WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object.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

Please indicate if you have any of the following:

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

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



IMPORTANT INSTRUCTIONS

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

Please consult the MRI Operator, MRI Scientist, or Director if you have any question or concern BEFORE you enter the MR system room.

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

Form Completed By: Subject Relative Nurse

Form Reviewed On ____/____/____

Form Reviewed By:

MR Scientist MR Operator Other _____

Print name

Signature

EXPIRES 4 WEEKS FROM APPROVAL ON ____/____/____

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Appendix 2 - MR Research User MRI Screening Form

WSU CoNECT RESEARCHER SCREENING FORM

I attest that the information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo. ANY CHANGES TO THIS FORM MUST BE REPORTED IMMEDIATELY

Date ____/____/____

Name _____

Age _____yrs

Weight _____lbs

Male Female

Principal Investigator/Supervisor _____ PI Phone # (____) ____-_____

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

2. Have you had a prior diagnostic imaging study or examination (MRI, CT, Ultrasound, X-ray, etc.)? No Yes

If yes, please list: Body part

MRI _____
 CT/CAT Scan _____
 X-Ray _____
 Ultrasound _____
 Nuclear Medicine _____
 Other _____

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

If yes, please describe: _____

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

If yes, please describe: _____

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

If yes, please describe: _____

6. Are you currently taking or have you recently taken any medication or drug? No Yes

If yes, please list: _____

7. Are you allergic to any medication? No Yes

If yes, please list: _____

8. Do you have a history of asthma, allergic reaction, respiratory disease, or reaction to a contrast medium or dye used for an MRI, CT, or X-ray examination? No Yes

9. Do you have anemia or any disease(s) that affects your blood, a history of renal (kidney) disease, renal (kidney) failure, renal (kidney) transplant, high blood pressure (hypertension), liver (hepatic) disease, a history of diabetes, or seizures? No Yes

If yes, please describe: _____

For female patients:

10. Date of last menstrual period: ____/____/____ Post menopausal? No Yes

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

12. Are you taking oral contraceptives or receiving hormonal treatment? No Yes

13. Are you taking any type of fertility medication or having fertility treatments? No Yes

If yes, please describe: _____

14. Are you currently breastfeeding? No Yes

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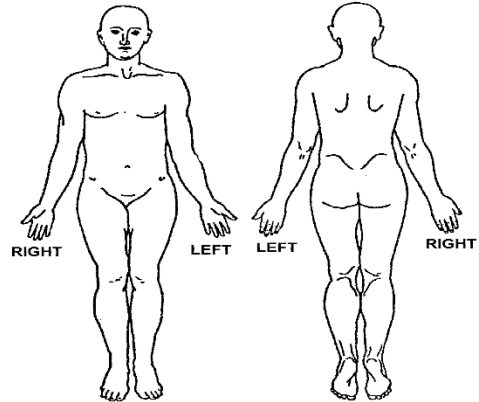


WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object.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

Please indicate if you have any of the following:

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

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



IMPORTANT INSTRUCTIONS

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

Please consult the MRI Operator, Director or MR Scientist if you have any question or concern BEFORE you enter the MR system room.

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

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

Form Completed By: Self Relative _____
Print name Relationship

Form Reviewed On ____ / ____ / ____

Form Reviewed By:

MR Scientist MR Operator Other _____
Print name Signature

EXPIRES 1 YEAR FROM APPROVAL ON ____ / ____ / ____

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Appendix 3 - MR Visitor MRI Screening Form

WSU CoNECT Visitor Screening Form



The MR system has a very strong magnetic field that may be hazardous to individuals entering the MR environment or MR system room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. Therefore, all individuals are required to fill out this form BEFORE entering the MR environment or MR system room. Be advised, the MR system magnet is ALWAYS on.

***NOTE: If you are a patient preparing to undergo an MR examination, you are required to fill out a different form.**

Date ____/____/____
month day year

Name _____
Last Name First Name

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

2. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, foreign body)? No Yes
 If yes, please describe: _____

3. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? No Yes
 If yes, please describe: _____

4. Are you pregnant or suspect that you are pregnant? No Yes



WARNING: Certain implants, devices, or objects may be hazardous to you in the MR environment or MR system room. **Do not enter** the MR environment or MR system room if you have any question or concern regarding an implant, device, or object.

Please indicate if you have any of the following:

- Yes No Aneurysm clip(s)
- Yes No Cardiac pacemaker
- Yes No Implanted cardioverter defibrillator (ICD)
- Yes No Electronic implant or device
- Yes No Magnetically-activated implant or device
- Yes No Neurostimulation system
- Yes No Spinal cord stimulation system
- Yes No Cochlear implant or implanted hearing aid
- Yes No Insulin or infusion pump
- Yes No Implanted drug infusion device
- Yes No Any type of prosthesis or implant
- Yes No Artificial or prosthetic limb
- Yes No Any metallic fragment or foreign body
- Yes No Are you going into the MRI system room?
- Yes No Any external or internal metallic object
- Yes No Hearing aid
(Remove before entering the MR system room)
- Yes No Other implant _____



IMPORTANT INSTRUCTIONS

Remove all metallic objects before entering the MR environment or MR system room including hearing aids, beeper, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry (including body piercing jewelry), watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, steel-toed boots/shoes, and tools. Loose metallic objects are especially prohibited in the MR system room and MR environment.

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

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form and have had the opportunity to ask questions regarding the information on this form.

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

Form Information Reviewed By: _____
Print name Signature

- MRI Operator Level 2 MR Personnel MRI Scientist Other _____

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