Safety Guidelines and Operating Procedures for Conducting Magnetic Resonance Imaging (MRI) Experiments Involving Human Participants

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TABLE OF CONTENTS

Introduction 1

Facilities 1

Principles of MRI Imaging 1

Primary Potential Risks Associated with MRI 5
- Projectiles/Missiles (Static Magnetic Field) 5
- Thermal Heating (RF Magnetic Fields) 6
- Burns (RF Magnetic Fields) 6
- Acoustic Noise (Gradient Magnetic Fields) 6
- Nerve Stimulation (Gradient Magnetic Fields) 6

Secondary Potential Risks and Concerns Associated with MRI 7
- Claustrophobia 7
- Asphyxiation 7
- Pregnancy 7
- Quench with Vent Failure 7

Risk Management 8

Emergencies 10
- Fire, Rescue, Police or Medical Emergency 10
- Contact with Bodily Fluids 11
- Visitors 11

Summary of Safety Guidelines 11
- I. Manuals 11
- II. Certification 11
- III. Line of Authority 11
- IV. Participant Policies 12
- V. Screening 12
- VI. Devices 12
- VII. Emergencies 12
- VIII. Visitors 13
- IX. Peripheral Nerve Stimulation and Other Sensory Effects 13
- X. Acoustic Noise 13
- XI. Radio Frequency Fields 14

References 15

Safety Guidelines and Operating Procedures for Conducting Magnetic Resonance Imaging (MRI) Experiments Involving Human Participants

Introduction

The purpose of this document is to define a set of safety standards and safety procedures for conducting magnetic resonance imaging (MRI) experiments involving human participants and biomedical studies at the Gateway MRI Center. The manual briefly describes the Center's Facilities, including the imaging modalities available. A brief description of the principles of MR imaging is provided as background to the risks associated with MR experiments. Subsequent sections are organized by topics that must be addressed before an investigator begins work at the Center. The requirements to be met before scanning include:

1) Obtain an MRI Center Operator Certificate (with current operator and safety training),
2) Obtaining approval of your study protocol from the Gateway MRI Center Director
3) For human studies, provide the Center with approval letter from the UNCG or A&T Human Research Protections Program & an approved Informed Consent form.
4) Establish an experimenter research file and participant screening files at the Gate MRI Center's administrative office.

The Gateway MRI Center adheres to the best practices, principles, and guidelines established by the American College of Radiology (Kanal 2013). The rest of this document takes highlights information that is relevant to the Gateway MRI Center operation and facilities.

Facilities

The Joint School of Nanoscience and Nanonengineering (JSNN) is located on the South Campus of the Gateway University Research Park just off I-40/I-85. We are currently located in Building 2 at 2907 E. Lee Street, Greensboro, NC 27401.

The JSNN Facility is a 105,000 square foot interdisciplinary research facility dedicated to academic and industrial research and development activities. The building has specialized nanotechnology resources, such as a nanobioelectronics cleanroom, nanocharacterization labs a computation and visualization facility and conventional science and engineering facilities under one roof. JSNN strives to provide an ideal teaming environment to facilitate interdisciplinary research in areas of nanobioelectronics, nanobiology including nanopharmacology, nanomaterials and nanocomputing.

The major JSNN resources are:

- Nanoelectronics and Nanobioelectronics Cleanroom
- Nanofabrication facility with nanoparticle synthesis, characterization, mixing and scale-up facilities
- Characterization suite, including NMR facility, **3T MRI scanner**, Analytical facility and Microscopy Lab
- Shared Nanoscience labs, including Nanobiology, BSL-3, Nanobiophysics, and Nanochemistry
- Visualization and Computing facility
- 232 seat auditorium

- Faculty, staff and graduate student offices
- Partner office and laboratory space
- Collaboration spaces, including small conference rooms and huddle spaces

Gateway Research Park has a Siemens Magnetom Tim Trio 3 Tesla MRI scanner. This scanner has a 60cm center inner bore diameter and a 50 cm spherical diameter imaging volume. The Tim Trio is equipped with water cooled gradient coils with a maximum gradient amplitude of 45 milliTesla/meter and maximum slew rate of 200 Tesla/meter/second. The scanner has a variety of RF coils to accommodate the broad imaging needs of the UNCG, A&T, and JSNN faculty. These coils include a 12 channel phased-array receive only head coil, a 15 channel transmit/receive knee coil, 16 channel bilateral breast coil, and Siemen's spine matrix coil.

The Gateway MRI scanner comes with the standard structural imaging capabilities found at a clinical MRI facility. The Tim Trio has parallel imaging capabilities to reduce scan time without affecting image quality. The scanner includes software packages for functional magnetic resonance imaging with prospective motion correction, diffusion tensor imaging, and susceptibility weighted imaging. The scanner is also equipped with Siemens BLADE acquisition software for improving the image quality of study participants who are prone to move during the exam.

All images acquired on the Siemens scanner are stored offsite behind the UNCG firewall on a secure PACS server. The PACS server currently has 1 Terabyte of available storage but its storage capabilities may be increased as necessary.

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Offline network storage with automatic backups is available to all UNCG investigators. This offline storage is mounted to a server with 16 cores (Xeon X5560) operating at 2.8 GHz with 8 Mbytes of internal cache and 64 GBytes total memory. The server is dedicated for scientific computing and will be used for analysis of all MRI data. Software packages already installed on this server include Matlab, FSL, Free Surfer, SPM8, CONN Toolbox, and ITK-SNAP.

The Gateway Joint School of Nanoscience and Nanotechnology building is ordinarily open weekdays from 8am – 6pm. The doors to this building are always locked. Access to the building requires either badge access or being met at the front door by someone with badge access. Visitors, defined as anyone with out a JSNN badge, must sign in and out in the visitors log located at the front desk. If you have a JSNN badge, you are required to sign the logbook when entering or leaving the building outside of normal operating hours.

To access the MRI Suite you must have completed your MRI safety training and been granted badge access to the MRI Suite. The doors to the MRI Suite should always remain closed. Under no circumstances should door be propped open or badge cards shared.

When a certified operator is not present in the MRI Suite, the door to the MRI Exam Room should remain locked. This includes times when the operator is leaving for just a short period of time. The crowd control tape should remain up at all times and should only be retracted when exiting or entering the MRI Exam room.

Principles of MR Imaging

Magnetic resonance imaging (MRI) is a highly flexible technique for making images of the human body. Hydrogen nuclei (protons) behave like small magnets, so that when a participant lies in a magnet the protons tend to align with the magnetic field. When properly excited the protons precess (rotate), producing a measurable signal in a nearby detector coil. The frequency of precession is proportional to the local magnetic field, so by making the field vary across the body the signals arising from different locations can be distinguished based on their frequency. There are three basic components to an MRI system:

- a large, static magnetic field (e.g., 3 Tesla for the human imagers at the Center);
- radio frequency (RF) coils that are used as a transmitter to excite the MR signal, and as a receiver to detect the MR signal; and
- gradient coils that are pulsed on and off to produce linear gradients of the magnetic field for imaging.

MRI techniques involve pulsing currents through the RF and gradient coils, so a particular technique is often referred to as a pulse sequence. By varying the pulse sequence, one can produce an enormous range of images with different spatial and temporal resolutions, and with substantially different contrast between tissues in the image.
Functional MRI (fMRI) is used to measure changes in blood oxygenation and blood flow that accompany neural activity. When a particular area of the brain is activated, the local blood flow increases dramatically and the local blood is more oxygenated. This change in oxygenation affects the local MR signal, so fMRI provides a way to map patterns of activation in the working human brain. In a typical fMRI experiment rapid dynamic images are acquired while a participant alternates between experimental and control conditions. The time series of images is then processed on a pixel-by-pixel basis to identify pixels that show a significant correlation with the alternating experimental and control periods.

The main magnetic field (e.g. 3 Tesla) is provided by a large magnet with a cylindrical bore with a diameter of 92.5 cm. Fixed within the bore is the gradient coil, with an inner diameter of 60 cm. A computer controlled bed moves in and out of the magnet bore to position the participant's head at the midpoint of the gradient coil. For brain imaging, the participant's head rests in the head RF coil, with an inner diameter of 38 cm. For functional MRI studies, three types of imaging are used:

1. Localizer: Brief images (about 20 seconds each) are acquired in three orthogonal planes in order to identify structural landmarks and choose the locations for imaging in the rest of the experiment. Typical time required is 1 min, although if re- positioning of the patient is necessary additional localizers may be required.
2. High resolution anatomical images: A 3D imaging sequence is used to acquire images of the entire brain at high resolution (e.g. 1x1x1 mm). The pulse sequence typically used is a 3D gradient echo, usually with an inversion preparation, which often typically requires 6-8 min.
3. Rapid dynamic imaging: Dynamic images are acquired while the participant performs the chosen task. Typically the pulse sequence used is an echo planar imaging (EPI) method with in-plane resolution of 3-4 mm, and a slice thickness of 3-6 mm. Typically each image is acquired after a single RF pulse, and the maximum image acquisition rate is about 12/sec. Each run of a dynamic series lasts from 3-8 min.

A full fMRI experimental session then consists of a localizer, one or more high resolution anatomical scans, and typically 3-6 dynamic imaging runs. Total time for the session ranges from 45-90 min.

Only individuals who have successfully gone through the Gateway's training program may perform MR scanning. There are four stages to this training program.

Operator Level 1) Basic Operation for scanning phantoms and inanimate samples.

OL1 requires that the operator to has successfully completed the MRI Safety Training, has read Gateway's Safety Procedures and Operating Guidelines, and understands the Gateway MRI safety procedures. Successfully completing OL1 training allows the OL1 operator to assist an OL4 operator in studies that have obtained IRB approval.

Operator Level 2) Basic Operation for scanning phantoms and inanimate samples.

OL2 requires that the operator to successfully complete OL1 training and Scanner Operation. An OL2 operator is permitted to scan phantoms and inanimate objects without supervision. If scanning objects and phantoms for studies the OL2 operator is responsible for making sure everyone involved in the study has gone through proper MRI safety training before being allowed in the MRI suite.

Operator Level 3) Preapproved Human Scanning.

OL3 requires that the operator complete OL1 and OL2 training, attend In-House MRI Safety lectures on human screening, read articles on MRI safety while scanning humans. OL3 allows individuals to scan individuals that are employees, staff, or students of UNCG, JSNN, A&T that have been preapproved by Gateways' MRI Director. A list of preapproved participants is maintained by the Gateway's MRI center.

Operator Level 4) Human Scanning

OL4 requires successful completion of OL3 training, pass a practicum test that covers basic operations for human scanning, covers human screening, and emergency procedures. Once a person is certified as an OL4 operator, he/she is able to schedule time on the scanner for technical development of MRI protocols and scanning human participants for research studies that have approved by the appropriate IRB.

Ongoing safety training is provided via an annual quiz which is retaken annually. In addition operators must be current with scanner policies and operating procedures within the prior 4 months. During MRI research studies the Center-Certified Operator has the on-site responsibility to implement all Gateway's MRI safety guidelines.

Primary Potential Risks associated with MRI

There are three basic components to an MRI system: a large, static magnetic field (e.g., 3 Tesla for the human imagers at the Center); Time Varying Radiofrequency (RF) Magnetic Fields are used to transmit and receive energy; and Time Varying Gradient Magnetic Fields are pulsed on and off to produce linear gradients of the magnetic field for imaging.

These three basic components are the source of five major risk factors associated with MRI.

Projectiles/Missiles (Static Magnetic Field)
The static magnetic field is always on. The static magnetic field is 100,000 times more powerful than the earth's magnetic field. Ferromagnetic objects will experience a strong attraction towards the magnet. This strong attraction of ferromagnetic objects can result in serious injury or even death. This is not an exaggeration. Name of Child was killed in 2001 when a oxygen bottle was brought into the MRI scanner. The oxygen bottle was attracted to the magnet with such force that it caused a fatal head injury.

To prevent damage or injury due to torsion or translational forces, all individuals who enter the magnet room must be prescreened to determine if they have any ferrous material in their body. Comprehensive safety screening reviews potential injuries involving ferrous material and the presence of ferromagnetic devices or implants (clips, screws, shunts, etc.) as well as cosmetic concerns such as permanent eyeliner, tattoos, hair weaves or braids, and permanent retainers.

Occasionally, participants will have been exposed to metal fragments (BBs, shavings, etc.). Metal bullets/shot/shrapnel in the head or torso are a contraindication to MRI. The only exception to this is implanted dental work in place for more than 6 weeks. Longstanding immobile bullets/shot/shrapnel in bones in the limbs are not a contraindication. Spinal rods or intramedullary rods older than 6 weeks are not a contraindication to MRI, but in these cases images quality may be significantly degraded depending on location. All jewelry and piercings should be removed.

The American College of Radiology (ACR) in the *ACR Guidance for Safe MR Practices: 2007 edition* has established guidelines and best practices for operating a MRI facility safely. The ACR divides an MRI facility into four distinct zones.

> ***Zone 1*** includes all areas accessible to the general public (the corridor outside the MRI Suite).
>
> ***Zone 2*** indicates the interface between publicly-accessible Zone 1 and the restricted Zones 3 and 4. The MRI screening room where participants are greeted and screened before entering the scanner room is ***Zone 2***.
>
> ***Zone 3*** is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death. ***Zone 3*** is strictly restricted. The MRI Console Room and MRI Equipment Room are ***Zones 3a*** and ***3b***, respectively.
>
> ***Zone 4*** is synonymous with the MR scanner laboratory, This includes anywhere the magnetic field exceeds 5 Gauss.

The floor plan of the Gateway MRI Center is such that there are only two zones after entering the door into the MRI Suite: Zone 3 and Zone 4.

These zones are clearly labeled.

The 5 Gauss line is exceeded outside the MRI scan room and proper precautions must be taken. All individuals entering the MRI Suite must be screened. Individuals taking a tour of the facility must be asked if they have any implantable device that would be affected by a magnetic field (pacemakers, aneurysm clips, etc.) If such individuals are identified in the group, they must not enter the MRI Suite.

Thermal Heating (RF Magnetic Fields)
Exposure to RF fields can cause tissue heating. The FDA has set guidelines the rate at which energy may be absorb by the body, known as the Specific Absorption Rate (SAR). As long as the scanner is operated within these guidelines there is no significant risk that the RF fields will cause tissue heating. Current MRI scanners, including the Gateway MRI scanner, predict and monitor the SAR in real time. The software will not allow you to exceed these limits. The SAR limits established by the FDA are time average limits. If the software detects the limits are exceeded, the software will delay the next scan until the SAR limits are once again in an acceptable range.

Burns (RF Magnetic Fields)
The interaction of the RF magnetic fields with conductive material can result in extreme local heating resulting in 1st, 2nd, and/or 3rd degree burns. To minimize the risk of burns all ferromagnetic and conductive material should be remove from the patient before entering the MRI Exam room. Conductive material such as cables and wires should be isolated from the participant.

Tattoos, permanent makeup, metal fragments in the extremities are not contraindications for MRI but special attention and care must be taken to minimize the risk of burns. The participant should be informed of the risk so he/she can tell you if they experience any heating. If such heating occurs the MRI scan should be terminated and participant should be excluded from the study.

An MRI compatible first aid kit is located in the MRI Exam room. Administer first aid as necessary.

Acoustic Noise (Gradient Magnetic Fields)
Rapidly switching the gradient magnetic fields on and off results in unintended mechanical vibrations capable of producing considerable acoustic noise within the scanner room, at some times registering up to 120 decibels (dB).

Participants in MRI studies are required to wear disposable foam ear plugs and/or headphones (both, when possible). Earplugs can reduce noise by 30dB. Other individuals who must remain in the room while scanning (e.g., parent or study coordinator) must also wear ear plug during the scan

Nerve Stimulation (Gradient Magnetic Fields)
The gradient coils used for imaging produce time-varying magnetic fields (slew rate in dB/dt). Such fields, if sufficiently strong, can produce peripheral nerve stimulation. Stimulation can occur in peripheral nerves, muscle, and blood vessels. The FDA guideline is that switched gradient fields pose a significant risk if dB/dt is sufficient to produce severe discomfort or painful stimulation.

The mean pain nerve stimulation threshold, the level at which half of participants are likely to report painful stimulation, is 90 Tesla/Second. The mean peripheral nerve stimulation threshold, the level at which 50% of participants might report a tactile sensation or metallic taste is 60 Tesla/Second. The slew rate of a typical scan is 45 Tesla/Second (see table above). Gradient

switching rates are limited in the pulse sequence software used for fMRI to insure that there is no discomfort for the participant.

Often participants may experience muscle twitching or spasm. This twitching may not be painful but can be disconcerting to the participant. Risk of peripheral nerve stimulation may be minimized by asking the participant not to cross their hands and feet while lying down on the scanner bed.

Following each scan session in which a participant reports any somatosensory, painful or motor stimulation, the participant should complete a peripheral nerve stimulation form

Secondary Potential Risks and Concerns associated with MRI

Claustrophobia
Some participants may exhibit anxiety when undergoing an MRI examination. These participants should be reassured that MRI is safe and given time to adjust. However, the participant decides when if he/she wants to be withdrawn from the study.

Asphyxiation
To reduce electrical resistance, superconductive magnets use cryogens to super-cool the electrical conductor that generates the static magnetic field. Temperatures of the cryogens used might be as low as -269o C (-452o F). Occasionally a sudden boil-off of all of the cryogen or a quench occurs. A quench is accompanied by a loud noise and causes the rapid loss of the magnetic field. Any helium or nitrogen gas that might leak into the magnet room could displace oxygen. The Center's magnet rooms are equipped with vents to properly dispose of cryogen vapors. However if the vents should fail, there is a risk of asphyxiation or frostbite. If the vents should fail during a quench the procedure in the following table should be followed. Essentially, the procedure involves turning on any remaining working fans and opening doors to the operator room and to the magnet room to permit the ventilation of helium or nitrogen gas from the magnet room. Next the participant should be removed from the magnet.

Pregnancy
Pregnant women will be excluded from studies at the Center. Although "to date there are no known deleterious effects related to the use of MR procedures during pregnancy" (Sawyer-Glover and Shellock, 2000), the FDA guidelines indicate that the safety of MR for imaging the fetus has not been established. Women of child-bearing age will be scanned only if the project was approved by the Institutional Review Board of the sponsoring institution. Age range and gender distribution of participants should be provided in the IRB application, along with methods to exclude pregnancy (questionnaire, pregnancy test, gender/age restriction…. etc.).

Quench with Vent Failure
A magnet quench can result in the release of cryogen vapor into the magnet room if white clouds of vapor appear in the magnet room. Cryogens released during a quench can cause asphyxiation, frostbite, or injuries due to panic. Magnet quenches are indicated by a loud noise, warning message, or the tilting of an image on the image screen. It is critical to have a well-planned method to quickly remove the patient and all personnel from the magnet room if a quench should occur.

Use this procedure in case of a sudden cryogen release into the magnet room.

1. Do not panic.

- Staying calm helps you remain focused so you are able to safely remember and follow your planned method of action.

2. **Using the intercom, tell the patient to stay calm and remain on the table.**
   - Tell the patient that someone will be in shortly to offer assistance.
3. **Turn on the magnet room exhaust fan.**
   - Some systems vent automatically and there is no fan to turn on.
4. **Prop open the door between the MRI Suite and the hallway to promote air circulation.**
5. **Prop open the door to the magnet room.**
   - If helium is venting in the room, the magnet room door may not open.
   - If the door cannot be opened, break the window to the magnet room to relieve pressure.
6. **Enter the magnet room and help the patient exit**
   - When exiting, stay near the floor where the oxygen will be and immediately exit the magnet room.
7. **Evacuate all personnel from the area until the air is restored to normal.**

(From GE Medical Systems MR 3.0T Signa Excite™ Learning and Reference Guide, 2003)

Risk Management

Operators must be trained and demonstrate competence in the operation of the MRI scanner. They must also be trained and demonstrate knowledge in risks of MRI and be able to respond appropriately to emergency situations should they arise.

Each examination will last approximately 1-1.5 hours. Prior to arriving at the Center, each participant is screened to make sure that there are no counter-indications for MRI (see checklist at the end). We recommend that participants are screened 3 times; (1) When the participant is first recruited for a study, the participant is initially screened for any contraindication to MRI. This early screening provides adequate lead time to investigate any “yes” responses on the screening form. It also prevents cancellation of scanner sessions due to participant incompatibility. (2) When the participant arrives at the Center, before entry into the magnet room every participant will again be carefully screened for any implanted material that could constitute a risk in the scanner. The participant will be asked to fill out a checklist again under the supervision of the Operator, and then each item will be verbally confirmed. If the participant is not sure about the answer to any of the checklist questions, they will not be scanned. **No one may enter the magnet room unless they have completed a screening form**. Participants attending for repeat investigations need to complete a new screening form. (3) Finally, immediately prior to taking the participant into the scan room, a third pre-procedure checklist is completed. This form is an “aide memoire” for the operator to clear the participant of any metal objects about their person / in pockets.

Pregnant women will be excluded from studies at the Center. Although “to date there are no known deleterious effects related to the use of MR procedures during pregnancy” (Sawyer-Glover and Shellock, 2000), the FDA guidelines indicate that the safety of MR for imaging the fetus has

not been established. Women of child-bearing age will be scanned only if the project was approved by the Institutional Review Board of the sponsoring institution. Age range and gender distribution of participants should be provided in the IRB application, along with methods to exclude pregnancy (questionnaire, pregnancy test, gender/age restriction…. etc.).

Any behavioral, physiological, or other equipment to be brought into the magnet room must be approved for MR compatibility by the Center Engineering team. MR compatibility must be documented on the Center's MR compatibility form, and the device must bear a tag to demonstrate that it has been approved (Appendix). Approved devices are positioned in the MRI scan room BEFORE the participant enters the scan room.

If there are no counter-indications for MRI, the participant will lie on the bed just outside the opening to the magnet and be positioned in the head coil. A step-by-step description of patient placement is found in the Appendix. A synopsis is presented here. The participant will be given ear-plugs and instructed in their proper use. For some studies the participant may also wear headphones. A button-press response box, mouse, or a joystick may be positioned where it can be manipulated by the participant. No cables should touch the participant's skin. Looped cables should not be placed near the participant. Any unused cables, transmit or receive coils, or any other unused equipment should be removed from the bore and from the RF coil. The bed is then advanced into the magnet through a computer-controlled interface.

If, at any time, a participant becomes unable to tolerate the procedure, the exam will be terminated. Participants will be in constant voice contact with the operator via an intercom system. Participants who cannot communicate reliably with the console operator should not be studied.

Although there are no known long-term cumulative effects of exposure to the electromagnetic fields used in MRI, it is prudent to limit the number of studies on a single individual. The recommended consent form includes asking the participant to specify the number of MRI examinations (either as a research participant or for medical purposes) they have undergone during the last year. Our recommendation is that investigators should limit studies on one participant to six within any one-year period. For some studies involving unique participants more studies may be required by the scientific goals of the experiment. In these cases a separate justification for the larger number of studies should be included in the IRB application and in the proposal sent to the Center.

MR is extremely safe and no adverse event is anticipated. As described above, the primary risk is from metallic objects brought into the scanner room that could become projectiles. To minimize this risk, nonessential personnel are excluded from the scanner room to insure that no ferromagnetic objects are brought near the magnet. In each scan room the 5 Gauss field limit is marked on the floor. No one may enter the magnet room unless they have been screened and checked for metal objects by the Center-Certified Operator running the console. National reviews of the few cases where metal objects caused injury during a scan have found confusion about who had the authority and responsibility to prevent metal objects from entering the scanning room.

At the Gateway MRI Center, the Center Certified Operator has the ultimate authority to enforce safety standards. Given the potential risks of peripheral nerve stimulation and over heating associated with rapid dynamic imaging, the Operator should frequently inquire about the participants comfort and room temperature. Typically some verbal contact should be made with the participant prior to each scan.

All records will be kept confidential. At the beginning of each study the Principal Investigator will provide the Operator with a participant ID for each participant. This number will be recorded in the computer database for that scanner, along with a record of each of the pulse sequences used for the study. This record will be archived. No identifying information will be stored except the number provided by the PI. In this way the participant's anonymity is preserved while allowing the Center to maintain records of the procedures used in each study.

Maintenance service on the system will follow Siemens guidelines. To reduce risks related to the static magnetic field, gradients, electromagnetic RF fields, and acoustic noise operators should follow the requirements outlined in the Summary of Safety Guidelines listed at the end of this manual.

Emergencies

If a metal object traps a participant in the magnet bore so that removal is not possible without quenching the magnet, press the Magnet Rundown System button on the side wall as one enters the magnet room (See Figure below). In about two minutes the magnetic field will drop to a level where metal objects can be removed. Although this is a measure of last resort, quenching is further justified if a participant has been injured. The Center is not a medical facility. Emergencies at the Center should be treated as they would in at any other medical emergency at JSNN.

In the event of a fire, rescue, police, or medical emergency at the Center:

1. Call 911 or 44357. This is Campus 911 not the general 911 number. The Operator will call the fire department, campus security, etc. In case the operator does not know the Center's location:

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   Joint School of Nanoscience and Nanotechnology
   MRI SUITE - Room L-111
   2907 E. Lee Street
   Greensboro, NC 27401
   Phone: 336-217-5159

2. Release the MRI bed from the scanner and pull it out from the scanner bore. Help evacuate the participant from the scan room quickly. In an medical emergency where the participant is unresponsive the two operators should remove the participant from the MRI scan room to the hallway outside the MRI scan room.
3. Administer CPR as needed. An Automated External Defibrillator is available in the hallway outside the MRI suite.

If a fire occurs in the magnet room (1) press the Emergency Off button. This is the red button on the upper right side of the console . There are also Emergency off buttons on each side of the front magnet facing. Pressing the button cuts power to the magnet room and removes electrical power to all components of the system other than the static magnetic field and the Magnet Shutdown Unit. (2) Evacuate the participant. (3) Pull the fire alarm and call Campus 911. (4) Use the fire extinguishers to contain the fire. Notice that the white extinguishers are in the magnet rooms and are magnet safe. **Red extinguishers should NEVER be taken into the magnet room**. The rule of thumb is to attempt to extinguish a fire that is not as tall as your waist. In the presence of a larger fire, evacuate all individuals to a safe location.

When the fire department arrives, center personnel must determine whether firefighters must take ferromagnetic objects into the magnet room. If ferromagnetic equipment must enter the room, quench the magnet by pressing the button on the Magnet Rundown Unit. The Magnet Rundown Unit is on the side wall as one enters the magnet room.

Contact with Bodily Fluids

The Center's general rule governing contact with bodily fluids is to take Universal Precautions (See Appendix). Universal Precautions begin with the assumption that all research participants harbor a contagious disease and that only trained staff should manage the clean up of bodily fluids. Several Center staff are being trained to clean up and dispose of small amounts of blood, urine, and other fluids. During normal working hours these staff can be contacted through the Center Director's Office

Visitors

Visitors are not permitted in the magnet rooms without prior approval of the Center Director.

Summary of Safety Guidelines

I. Manuals

The Gateway's MRI Operator's Manual should be in the control room whenever a participant is run.

II. Certification

All console operators must complete the center's operator training and safety courses and updates.

All console operators must earn and maintain a Center Certified Operator certificate.

To maintain active Certification an operator must maintain safety training via the annual quiz and regularly perform research scans at Gateway's MRI Center (minimum of 4 months currency). The Center Director will monitor operator activity. If an operator does not meet the 4 month minimum requirement he/she must be reapproved by the Gateway's MRI Director.

Research assistants who are not operators, but are essential to the running of a research study may enter the scan room, providing they are safety trained – having taken the Center safety lecture, the annual safety quiz and any updates.

III. Line of Authority

Everyone in the magnet suite has the responsibility to insure safety.

The Center-Certified Operator running the console has the ultimate AUTHORITY to enforce safety standards.

The Center-Certified Operator running a study is that operator listed in the web- based scheduling program. Any changes to the operator for a particular study MUST be reflected in the scheduling program.

No one may cross into the magnet room without approval from the Center- Certified Operator.

IV. Participant Policies

Only individuals who can be studied without anesthesia may be scanned at the Center. Women of child-bearing age may be studied at the Center only for protocols that have IRB approval. The submitted IRB protocols must include the proposed age range and gender distribution of participants to be studied, and the means to establish that a participant is not pregnant.

Studies involving pregnant women or patients taking fertility treatments must be specifically approved by the IRB of the sponsoring institution.

All research participants may be scanned only after obtaining an approved IRB protocol.

Participants with metal fragments in brain, eye, auditory canal, spinal cord, or internal organs may not enter the magnet room.

Participants who screen positive for shrapnel or bullets outside of the areas mentioned above may be studied after documenting the location of the objects on the anatomical diagrams included in the screening checklist. As with all participants, these individuals must be monitored for temperature comfort.

Participants with whom no reliable communication can be maintained may not be scanned at the center.

In the event of an accident that might expose any research participant or research personnel to body fluids universal precautions should be followed. Universal precautions stress that all individuals should be assumed to be infectious for blood-borne diseases such as hepatitis B. A description of universal precautions is contained in the appendix.

V. Screening

Participants should be screened for the presence of implanted or attached medical devices or other objects. The screening should use approved forms and occur during recruitment into a study and each time a participant enters the magnet room.

Only a Center Certified Operator should perform the screening prior to a study.

Any patient with diminished cognitive competence should be screened with a hand-held metal detector to determine if they have overlooked metal on their person.

Individuals who screen positive for implanted or attached medical devices should not be allowed into the magnet room unless prior approval is obtained from the Center Director and Safety Officer.

To permit an individual who screens positive for implanted or attached medical devices, to enter the magnet room requires the name of the device, its manufacturer, and its part number. After the device is identified, documentation of its MR compatibility and safety is required.

VI. Devices

The Gateway's MRI Director must review and approve the safety of any behavioral or physiological device entering the magnet room.

Device approval must be documented using the MR Device Compatibility Form, and tagged to show they have been approved

Approved devices must be positioned in the scan room BEFORE any participants are positioned on magnet table, or in the vicinity of the magnet.

Special care will be given to positioning of any wires attached to the device. Wires should not touch the research participant. Wires should be kept straight and not contain loops.
Remove unused transmit or receive coils from magnet bore and bed.

VII. Emergencies

Release table latch and pull participant out of the bore.

Release MR bed and roll it into the hallway between the 3T scanners. All Center trained operators must have experience with this maneuver before being certified.

Call 911.

We do not support a crash cart.

Administer CPR as needed. An AED is available in the hallway outside of the MRI Suite**. The AED is not MRI Compatible and can not be used in the MRI Scanner Room**. **Participant must be removed from the MRI Scanner Room before using the AED.** All operators must have current CPR certification.

Use the Safety Kit to manage minor injuries. Gloves should be used when managing minor cuts.

Manage fires with the white extinguisher. Turn off electrical power to the scanner with the red emergency buttons on the console, or body of the scanner. Close doors to contain smoke/flames.
Do not quench ("emergency run down") the magnetic field unless a participant is trapped by a metallic object in the scanner and is injured or in danger of becoming injured.

VIII. Visitors

Visitors are not permitted inside the magnet rooms without permission of the Center Director.

IX. Peripheral Nerve Stimulation and other Sensory Effects

If the patient complains of pain or discomfort including headache stop the scan immediately. If the pain is not due to a biomechanical cause (awkward placement of body, poor placement of neck or head supports, etc.) terminate the study. If the discomfort is due to a biomechanical cause, the study may continue if the cause is corrected.

If the patient complains of tingling, a light touch sensation, or muscle twitching stop the scan and access the extent of discomfort. If the discomfort cannot be minimized, the study must terminate.
When giving informed consent and, again, prior to entry into the magnet room, participants will be informed of the possibility that they should report to the scan operator excessive warmth, visual flashes, dots, scintillations, or tactile sensations during an MR study.

X. Acoustic Noise

All individuals entering the magnet bore must be provided adequate sound protection. Earplugs and headphones can attain this standard. (< 99 db of audible noise).

When earplugs are used to provide sound protection, only center-approved earplugs should be used.

Dispose of earplugs after each participant is scanned.

XI. Radio Frequency Fields

Each person's weight must be entered into the appropriate program field before starting a scanning session. This is a critical safety step.

The patient fan should be ON at all times to maintain adequate airflow through the bore.
The Console Operator should inquire whether the participant is too warm or cold periodically during the study.

Participants should not be scanned if they have damp clothing, come in contact with the RF circuitry of an RF coil surface, come into contact with a looped wire, or if unconnected receive coil or other cables have not been cleared from within the RF transmit coil.

Use non-conducting pads when needed. Position the participant's hands to the side and insure that legs are not crossed.

Place foam between the participant and the bore.
When using surface coils place a sheet or pillowcase between the coil and the patient's skin.

Participants with permanent eyeliner or other metallic ink tattoos may be scanned only after obtaining informed consent under an approved IRB protocol. Such participants must be informed of the risk of skin irritation. Maintain close communication with these participants during the course of the scan, and be ready to terminate the exam if symptoms develop.

Jewelry should be removed prior to a scan. On a case by case basis the Console Operator may decide whether rings may be worn during a scan.

Scans should not be performed if the magnet room is warmer than 21° C (70° F).

Do not interfere with the performance of the RF power monitor.

Head studies producing SAR values greater than 3.2 Watts/kg must be approved by the Center Director and have IRB approval.

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International Electrotechnical Commission: www.iec.ch

Shellock/Baccaco MRI Safety website: www.MRIsafety.com