George Mason University
Krasnow Institute for Advanced Study
MRI Suite
Safety and Operations
Policies and Procedures Manual

Prepared by:
Environmental Health and Safety Office
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Acronyms

0.5 mT	5 Gauss Line
ACR	American College of Radiology
AED	Automated Emergency Defibrillator
ARRT	American Registry of Radiologic Technologists
BLS	Basic Life Support
CPR	Cardiopulmonary Resuscitation
dB	Decibel
EHS	Environmental Health and Safety
FDA	Food and Drug Administration
IRB	Institutional Review Board
KRASNOW	Krasnow Institute of Advanced Study
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
NICKI	Neuroimaging Core of the Krasnow Institute of Advanced Study
ORIA	Office of Research Integrity and Assurance
PI	Principal Investigator
RF	Radio Frequency
SAR	Specific Absorption Rate
SOP	Standard Operating Procedure
T	Tesla
W/kg	Watt/kilogram

Foreword

The purpose of the *George Mason University Krasnow Institute for Advanced Study MRI Suite Safety and Operations Policies and Procedures Manual* is to provide a resource for safe MRI practices at George Mason University. The safety policies and procedures outlined in this manual are based on recommendations of the American College of Radiology (ACR), guidance from the Food and Drug Administration (FDA), and best practices. The ACR 2007 publication, *ACR Guidance Document for Safe MR Practices 2007*, www.acr.org, was used as a primary reference for development of the MRI Safety Program at George Mason University.

The policies and procedures discussed in this manual were developed through the cooperative efforts of the Environmental Health and Safety Office (EHS), Office of Research Integrity and Assurance (ORIA), Office of Risk Management, the Director of the Krasnow Institute of Advanced Study (Krasnow Institute), and the Neuroimaging Core of the Krasnow Institute of Advanced Study (NICKI).

This manual is available in the MRI Suite located in the Krasnow Institute and is posted on the EHS (ehs.gmu.edu) and NICKI (http://krasnow.gmu.edu/nicki) websites. The contents of this manual are reviewed annually and revised as necessary to reflect changes in MRI safety and operations.

This manual supersedes all previous manuals regarding MRI policies and procedures.

Document History

Version	Date	Comments
1	2007	Initial MRI Policies and Procedures Manual
2	January 2010	Revision of initial MRI Policies and Procedures Manual
3	February 2011	Review and Revision of MRI Policies and Procedures Manual (version 2 – January 2010)
4	June 2013	Review and Revision of MRI Policies and Procedures Manual (Version 3 – February 2011)

1.0 Introduction

The MRI Suite at the Krasnow Institute is dedicated to providing resources for the acquisition and storage of brain image data to the neuroscience community. George Mason University encourages collaborations between institutions and scientists, disseminates products of our research, and shares the resources of the imaging suite.

The MRI Suite contains a high field 3 Tesla Siemens Allegra MRI scanner. This magnet is a head-only scanner designed to accommodate high resolution structural and functional imaging of the human brain. It has the capacity to resolve specific images of gray and white matter tissue and brain structures, vasculature, basic metabolic chemistry, and functional neural systems present in the human brain.

Because of the inherent risk associated with MRI, George Mason University follows strict safety and operational procedures to protect the health and safety of all personnel and participants who enter the MRI Suite. These procedures, as well as programmatic, maintenance, and operational requirements of the MRI Suite, are outlined in this manual.

1.1 Basis of Magnetic Resonance

Magnetic resonance (MR) tomography uses the magnetic characteristics of certain nuclei in the body, and especially the hydrogen nucleus (proton) to generate images. It is based on the premise that these nuclei exhibit a magnetic moment. The hydrogen atom is an elementary part of water and fat and is, therefore, the most prevalent element in the human body. When a person is placed in the scanner, the magnetic movement of the hydrogen nuclei aligns with the direction of the magnetic field. A radio frequency (RF) field is briefly turned on and off to cause the magnetic moment to realign briefly. The scanner detects the motion of the magnetic moments of the protons as they return to their equilibrium position along the strong magnetic field of the scanner.

Functional MRI measures signal changes in the brain, resulting from increased blood consumption in areas of increased neural activity. The brain is scanned at low resolution at a rapid rate (once every two-to-three seconds); differences between the images are used to detect the presence of activity.

1.2 Static Field Strength

When the MRI scanner is on, the static magnetic field (the main magnetic field of the scanner) is always present. Magnetic field is measured in units of Tesla (T). One Tesla equals 10,000 gauss, and is 20,000 times stronger than the magnetic pull of the earth. Field strength increases in a nonlinear manner as an object gets closer to the bore (or center) of the magnet. The magnetic attraction of the MR scanners for ferromagnetic objects can result in a missile or projectile effect as these objects are pulled toward the bore of the magnet with great force. In addition to the hazard of projectiles, the static magnetic field can cause ferromagnetic objects within the body (such as aneurism clips, metal slivers, etc.) to move or torque, resulting in potentially serious injury.

The static field can also disrupt the function of electrically, magnetically, or mechanically activated implants such as pacemakers. The closer a pacemaker is to the magnet; the more likely it is to become completely dysfunctional. For this reason, all MRI manufacturers are required to identify a 5-gauss pacemaker exclusionary zone to avoid the possibility of pacemaker dysfunction. This exclusionary zone extends from the center of the magnet in all directions to the distance at which the field strength equals 5 gauss (0.5 mT).

1.3 Risks Associated with Magnetic Resonance Imaging (MRI)

1.3.1 Missile Effect

The missile effect or projectile effect refers to the capability of the fringe field of the static magnetic field to attract a ferromagnetic object, drawing it rapidly into the scanner with considerable force. When this occurs, the missile effect can pose a significant risk to anyone in the path of the projectile, and cause significant damage to the scanner.

To guard against accidents from metallic projectiles, the 5 gauss line should be clearly demarcated and the area with that line kept free of ferromagnetic objects. Personnel and research participants must remove all metallic personal belongings (hearing aids, analogue watches, jewelry, belts, etc.) before entering the magnet room, as well as any clothing with magnetic fasteners.

All equipment to be taken into the scanner room, housekeeping supplies (bucket, broom, mop, etc.), research equipment (props), tools, and emergency equipment (litter, fire extinguisher, etc.) must be made of nonferrous material and be classified as MR safe.

1.3.2 Rotational and Translational Forces

Rotational force is a force that causes a ferrous object to turn and align along the magnetic field. Translational force is a force that causes a ferrous object to be pulled toward the center of the magnet.

Implants and devices that are not proven MR safe pose a serious health risk due to torque and heating. Implants tested to be safe at 1.5 T are not necessarily safe at 3 T. All implants and devices must be documented as MR safe before being permitted in the MRI Suite. Information and guidelines can be found at www.MRISafety.com.

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.

1.3.3 Cryogenic Liquids

The coils of the superconducting magnet are immersed in liquid helium to prevent excessive heat buildup. Under normal operation, the helium slowly boils off and more liquid helium must be

added. Risks associated with liquid helium include burns due to accidental direct contact with the cryogen or hypoxia as a result of a leak or quench.

A quench involves the rapid release of helium and results in loss or decrease of the magnetic field. A manual quench can be performed by trained personnel in the event of an emergency, such as a person being pinned to the magnet. In extraordinary circumstances, an uncontrolled quench can occur. In this circumstance, the oxygen level in the magnet room may significantly decrease, causing a hypoxic environment. To reduce the risk of hypoxia due to the rapid release of helium, the laboratory that houses the magnet has adequate ventilation and the doors open in the path of egress.

1.3.4 Magnetohydrodynamic Effect

Magnetohydrodynamic effects are phenomena that arise from the motion of electrically conducting fluids (like blood) in the presence of electric and magnetic fields. These effects become more evident with an increase in static magnetic field strength. Within the MRI environment, magnetohydrodynamic effects may cause vertigo, nausea, or phosphenes (visual sensation from electrical stimulation of the eye).

1.3.5 Radiofrequency Fields

The MRI signal is created by RF pulses through a transmit core. Conducting materials within the RF field may result in a concentration of electrical currents sufficient to cause excessive heating and tissue damage. Absorption of RF power by tissue is described in terms of Specific Absorption Rate (SAR) which is expressed in watts/kilograms (W/kg). According to the FDA, the SAR must be no greater than 4 W/kg averaged over the whole body for any 15-minute period, 3 W/kg averaged over the head for any 10-minute period, 8 W/kg in tissue in the head or torso, or 12 W/kg in tissue in the extremities for any period of 5 minutes.

1.3.6 Acoustic Noise

Movement of the gradient coils due to switching of the gradient magnetic field is the main source of considerable acoustic noise within the scanner room, registering up to 140 decibels (dB).

Participants in MRI studies are required to wear disposable foam ear plugs and/or headphones (both, when possible). Ear plugs can reduce noise by 30dB. Other individuals who must remain in the room while scanning (e.g., parent) will also be given earplugs.

1.4 Facility Design

1.4.1 Safety Zones

The area where the MR scanner is housed is divided into four safety zones in accordance with the *ACR Guidance for Safe MR Practices: 2007*. *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, that is, the physical confines of the room within which the MR scanner is located. *Zone 4*, by definition, will always be located within Zone 3 as it is the MR magnet and its associated magnetic field that generates the existence of Zone 3. The 5 gauss line extends into the console room (Zone 3A) along the wall shared with Zone 4, and is clearly marked with tape. Zones 3 and 4 comprise the MRI Suite (Figure 1).

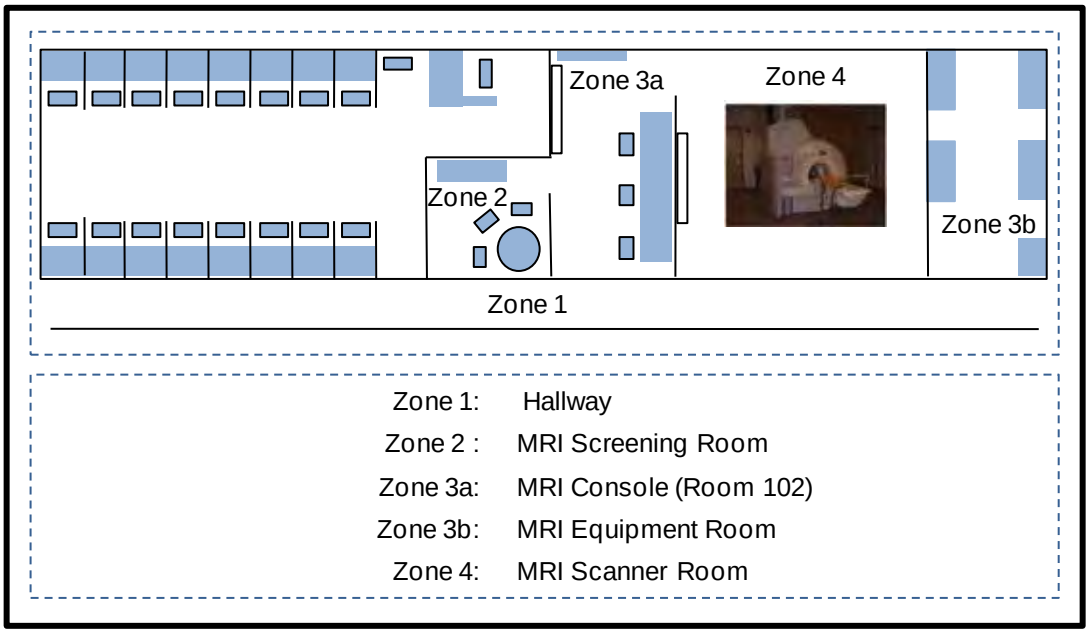


Figure 1. Krasnow Institute Magnetic Resonance Imaging (MRI) Safety Zones

1.4.2 Shielding

The scanner room (Zone 4) is shielded on six sides by copper and steel. The wave guides which permit functional imaging equipment to attach to the MRI are also constructed of copper. The copper shielding protects the magnetic environment from outside RF contamination. The steel shielding contains the magnetic field so that the hallway (Zone 1 – public access) is free of the magnetic field. The 5 gauss (0.5 mT) line extends into the console room to an area approximately 3 feet wide and 1 foot deep. Therefore, anyone with a pacemaker is not permitted entry to the console room. The presence of this field poses no risks to others who are certified to enter the console room. Appendix A shows a diagram depicting the 0.5 gauss line.

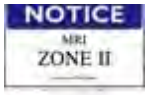
1.4.3 Ventilation

The MRI Suite has unidirectional laboratory ventilation. In the event of a quench, released helium is vented to the building exterior to prevent the creation of a hypoxic environment. Quench is accompanied by a loud noise, which would startle persons in the facility and surrounding area. The helium released to the outside air is not toxic or harmful.

1.4.4 Signage Requirements

All MRI facilities are required to have clear signage that indicates the hazards present and access restrictions. Figure 2 illustrates the signage posted at each zone.

Zone 1 is posted on the wall in the hallway between the MRI Console Room door and the MRI Computer Room door.



Zone 2 is posted on the door of the Screening Room located next to the Console Room door.

Zone 3 is divided into 3A and 3B. Zone 3A is posted on the outside of the MRI Console Room door and Zone 3B on the outside of the MRI Computer Room door.

Zone 4 is posted on the door to the Scanner Room. This sign is only visible in the Console Room.

Figure 2. Zone Signage

Figure 3 illustrates signage in place at the entrance to the MRI Console Room.

A sign is posted on the external door in the hallway (Zone 3) to the MRI Console (Zone 3a) warning of the high magnetic field and prohibition of anyone with a pacemaker or other electronic implant to enter the room.

There is also a rug placed in front of the door conveying the message that the magnet is always on.

There is a lighted sign posted in the hallway to the right of the console room door which displays, "The Magnet is On."

Figure 3. Magnetic Resonance Imaging (MRI) Console Room Entrance Signage

1.4.5 Labeling Requirements

Equipment, instruments, and devices should be clearly labeled to indicate their safety in the MR environment. Three types of labels (Figure 4) can be used to indicate if an object is safe for the MR environment (MR safe), safe under specific conditions (MR conditional), or unsafe (MR unsafe).

Figure 4. ASTM Labeling

MR safe is defined as an object that poses no known hazards in all MR environments. MR safe can only be applied to objects that are 100% safe to be taken, used, or placed within all MR environments without any risk or potential harm.

MR conditional is defined as an object that is safe when used in a specific manner within specific MR environments. Most objects will receive this rating. An object with this label warns the user that there are limitations to the usability or to the testing that was performed on it. In other words, the object may have been tested for a 1.5 Tesla system, but not for a 3-Tesla system. The conditions should be included on the object, in its packaging, or its accompanying instructions.

MR unsafe is defined as an object that poses a known threat or hazard in all MR environments.

1.4.6 Equipment

The MRI Suite is equipped with MR safe supplies for housekeeping, an MR safe ladder, two MR safe fire extinguishers located in the scanner and console rooms, and an MR safe stretcher in case of a medical emergency. A portable Automated External Defibrillator (AED) is located in the upper level of the institute near the entrance doors next to the elevator. The AED is not MR safe and, therefore cannot be brought into the MRI Suite. All equipment is labeled regarding suitability for the MR environment.

2.0 Roles and Responsibilities

It is the responsibility of all employees, students, and visitors to conduct activities in a manner that will not adversely impact themselves, other laboratory personnel, George Mason University property, the surrounding community, or the environment. The implementation of a comprehensive MRI safety program relies on the support and cooperation of all entities listed in this section.

2.1 Vice President for Research and Economic Development

The President delegates authority to the Vice President for Research and Economic Development, who is charged with overseeing all aspects of compliance with regard to health and safety. Specific responsibilities of the Vice President for Research and Economic Development with regard to MRI safety are to:

- Approve and oversee all plans, policies, and procedures related to compliance with regard to environmental health and safety for instruction and research at George Mason University;
- Oversee the EHS Office and the ORIA;
- Coordinate with the Director of Krasnow Institute and the Director of Laboratory Safety/Environmental Compliance regarding the appointment of the MRI Safety Manager; and
- Oversee the MRI Policies and Procedures Committee.

2.2 Director of the Krasnow Institute

The Director provides the necessary support for proper management of maintenance and operations of the MRI Suite and supervises the MRI Safety Manager with respect to maintenance and operations. Specific responsibilities with regard to the MRI Suite are to:

- Serve as an ex-officio member of NICKI.
- Supervise the MRI Safety Manager with respect to operation of the MRI Suite.
- Provide the necessary support for proper management of maintenance and operations of the MRI Suite.
- Ensure compliance with George Mason University safety policies and procedures.
- Negotiate and manage research contracts for research and development activities conducted in collaboration with vendors, as well as service and maintenance contracts.
- Serve as member of the MRI Policies and Procedures Committee.
- Oversee financial mechanisms for billing and purchasing.
- Maintain service contracts for the MRI Suite.
- Report instances of noncompliance (failure to exercise and implement safety policies and procedures or failure to adhere to IRB protocols) to EHS and/or ORIA.

2.3 Director of Laboratory Safety/Environmental Compliance

The Director of Laboratory Safety/Environmental Compliance oversees development and implementation of safety and compliance programs for George Mason University's research and instructional laboratories, to include the MRI Suite. Specific responsibilities with respect to the MRI Suite are to:

- Serve as an ex-officio nonvoting member of NICKI;
- Supervise the MRI Safety Manager with regard to development and implementation of the MRI Safety Program;
- Provide necessary support for development and implementation of the MRI Safety Program;
- Serve as a member of the MRI Policies and Procedures Committee; and
- Conduct routine review of the MRI Safety Program for compliance with policies and procedures.

2.4 Assistant Vice President for Research Compliance

The ORIA oversees compliance with all regulations regarding the use of research subjects or participants and coordinates the activities of George Mason University's IRB and the Institutional Animal Care and Use Committee. Specific responsibilities with regard to MRI Suite are to serve as a member of the MRI Policies and Procedures Committee.

2.5 Director of Risk Management

The Office of Risk Management administers the Commonwealth's Risk Management Plan and supports George Mason University departments by assessing potential risks, recommending action to manage hazards, or suggesting controls to minimize certain risks. Specific responsibilities of the Office of Risk Management are to serve as a member of the MRI Policies and Procedures Committee and participate as needed in the Device and Implant Safety Committee.

2.6 Neuroimaging Core of Krasnow Institute (NICKI)

The NICKI Board consists of faculty and research fellows at George Mason University who conduct research using various neuroimaging methods. The overarching role of NICKI is to promote the application of MRI techniques to neuroscience research and to provide scientific governance and selection of MRI experimentation that occurs in the MRI Suite. Specific responsibilities of NICKI are to:

- Review MRI projects involving human participants prior to IRB approval;
- Review projects involving phantom scans and scanning of inanimate objects for appropriateness of design;
- Review requests for validity testing;
- Ensure that all project proposals reviewed by NICKI follow George Mason University policies and procedures regarding MRI safety and operations;

- Appoint a Faculty Ambassador for the MRI;
- Participate in the development of policy regarding MRI operations;
- Serve as a resource for researchers interested in sharing MR data, methodologies, sequences, and scanning solutions;
- MR data transfer between on-campus buildings; and
- Design and implement pilot grant program which provides scanning funds for investigators new to MRI research.

2.7 Faculty Ambassador

The Faculty Ambassador is appointed by NICKI to serve as a liaison between faculty, the MRI Safety Manager and the Director of the Krasnow Institute. The faculty ambassador will serve a term of 3 years and may be re-elected to consecutive terms. Specific responsibilities are to:

- Serve as a member of the MRI Policies and Procedures Committee.
- Maintain and update the NICKI website.
- Serve as an advocate for MRI Operators with regard to MRI operations.
- Serve as Faculty representative for scheduling and financial aspects of scanner use.

2.8 MRI Policies and Procedures Committee

The members of the MRI Policies and Procedures Committee are appointed by the Vice President for Research and Economic Development and include faculty representatives from NICKI, the Director of the Krasnow Institute, the Director of Laboratory Safety/Environmental Compliance, the MRI Safety Manager, the Assistant Vice President for Research Compliance, the Faculty Ambassador, the MRI Physicist, and the Director of Risk Management. Responsibilities of the committee are to:

- Develop policies regarding safe operation of the MRI Suite;
- Establish procedures appropriate for implementation of MRI policies;
- Conduct annual review of the *MRI Policies and Procedures Manual*;
- Review requests to modify the MRI policies and procedures;
- Participate in incident investigations for incidents taking place at the MRI Suite; and
- Oversee development of the MRI Training Program.

2.9 Device and Implant Safety Committee

The Device and Implant Safety Committee reviews implants and devices to assess MR compatibility. The committee is comprised of the MRI Safety Manager and the MRI Physicist, and will involve other personnel such as the Director of Risk Management and a consulting radiologist as necessary.

2.10 MRI Safety Manager

The MRI Safety Manager is an American Registry of Radiologic Technologists (ARRT) registered professional with the knowledge and experience to oversee day-to-day operations of

the MRI Suite and implement George Mason University's MRI Safety Program. The MRI Safety Manager's primary function is to support the research activities conducted within the MRI Suite by George Mason University Principal Investigators (PI) while overseeing the safe operation of the MR Scanner and compliance with all relevant regulations, and George Mason University policies and procedures. The MRI Safety Manager is appointed by the Vice President for Research and Economic Development following consultation with the Director of the Krasnow Institute and the Chair of NICKI and the Director of Laboratory Safety/Environmental Compliance. The MRI Safety Manager reports to both the Director of the Krasnow Institute and the Director of Laboratory Safety/Environmental Compliance. The dual reporting relationship for this position is in place as a means to avoid conflicts of interest between the operational needs of the facility and compliance responsibilities.

To ensure safety and compliance with policies and procedures, the MRI Safety Manager will implement the MRI Safety Program. This position has the authority to immediately cease or suspend unsafe activities or activities that are out of compliance with George Mason University policies and procedures and applicable regulations, and will report such instances for further review to the Director of Laboratory Safety/Environmental Compliance and the Director of the Krasnow Institute. Responsibilities are to:

- Maintain appropriate certifications to include ARRT certification and Basic Life Support (BLS);
- Maintain current knowledge of functional MRI protocols utilized in the MRI Suite and be able to assist investigators in setting up new protocols;
- Serve as ex-officio member of NICKI;
- Monitor and implement policies and procedures for safety and operations of the MRI Suite;
- Implement the MRI Safety Program and require compliance with all relevant policies, procedures, and regulatory requirements regarding MRI safety and operations;
- Maintain currency, through additional training and attendance at workshops if necessary, in functional MRI protocols such as echo planar imaging to serve the needs of PI conducting scientific research with the MRI scanner;
- Make sure all necessary service contracts are in place for service and maintenance, and that service is carried out according to the recommended schedule;
- Oversee development and implementation of MRI training for George Mason University personnel in cooperation with the MRI Policies and Procedures Committee;
- Oversee service and maintenance for the MRI Suite and coordinate with service engineers as necessary regarding service and maintenance;
- Coordinate with Facilities, EHS, and University Police as necessary regarding maintenance, safety, incident response, and security of the MRI Suite;
- Conduct routine instrument testing and calibration, in consultation with an MRI Physicist member of NICKI;
- Coordinate monthly and expedited reviews for incidental findings, supplying the neuroradiologist with structural scans for review, conveying findings to PI, and maintaining records of such notifications;
- Oversee scheduling and maintain calendar for the MRI scanner and Mock Scanner Room;

- Coordinate with the Finance Manager of the Krasnow Institute to facilitate billing and maintain records for scanning time and use of the facility;
- Maintain documentation and records for safety and compliance, training, service and maintenance, participant screening, quality assurance data, and incidental findings;
- Cease or suspend unsafe activities and instances of noncompliance until the issues can be resolved and corrective actions taken;
- Report unsafe activities and issues of noncompliance to the Director of Laboratory Safety/Environmental Compliance, the Director of the Krasnow Institute, and the Chair of NICKI;
- Conduct safety screening of all users of the MRI Suite as a component of MRI safety training and approve or deny access to the suite based on training proficiency and screening results;
- Respond to incidents and emergencies as needed during and after normal work hours;
- Maintain supply of disposable equipment and supplies for the MRI Suite;
- Supervise the part-time MRI Technologist;
- Serve as full-time MRI Technologist; and
- Maintain participant database.

2.11 MRI Technologist

The MRI Technologist works directly with users and study participants to perform structural and functional scans. The MRI Technologist is an ARRT-registered technologist responsible for operating the Siemens Allegra 3T MRI scanner, screening participants prior to scanning, preparing participants for their scan, providing immediate medical treatment and assistance when necessary, responding to incidents and accidents within the MRI Suite, and processing (reformatting, maximum intensity projections, etc.) and maintaining MRI data. Specific responsibilities of the MRI Technologist are to:

- Maintain current ARRT certification;
- Maintain Cardiopulmonary Resuscitation (CPR) and BLS certification;
- Restrict access to the MRI Suite to authorized individuals and participants;
- Conduct safety screening for research participants and guests accompanying participants;
- Respond to after-hours emergencies as needed;
- Perform routine cleaning and maintenance of the MRI facility (includes cleaning floors and surfaces, replacing light bulbs in the ceiling of the MRI scanner room, leaving the trash can outside of the facility in the main hallway to be emptied by housekeeping staff);
- Operate the MRI scanner to include routine and experimental setup, modification of scanning parameters to optimize data, daily quality assurance testing, and basic troubleshooting of scanner malfunction;
- Greet and interview research participants, document screening interviews, prepare subjects for scanning, converse with subjects during scanning, remove subjects from the scanner after scanning, and conduct follow-up interviews with subjects after scanning;
- Respond to any incidents or accidents that occur within the MRI Suite;
- Maintain accurate and appropriate records of the usage of the MRI scanner and of participant studies;

- Support users of the MRI scanner with paradigm implementation and other needed assistance;
- Enforce safety policies in the MRI Suite;
- Organize, archive, and facilitate the transfer of acquired imaging data; and
- Monitor and maintain temperature requirements for the scanner (water and helium levels).

2.12 Principal Investigators (PI)

PIs, as defined in University Policy 4012, are responsible for overseeing the activities of all Research Assistants assigned to execute their MRI experiments. It is the responsibility of the PI to follow MRI policies and procedures and to ensure that personnel training is completed. Specific responsibilities of PI are to:

- Require that all projects for which they are responsible comply with relevant regulations, policies, and procedures for use of the MRI and for human subjects research;
- Obtain the appropriate approval from NICKI and the IRB for conducting research in the MRI scanner;
- Require that all MRI operators involved in their research maintain training requirements, and follow all relevant MRI policies and procedures and IRB requirements;
- Communicate instances of accidents and unsafe work conditions to the MRI Safety Manager and the IRB;
- Notify research subjects of incidental findings and report findings to the IRB in accordance with George Mason University policy;
- Implement and ensure compliance with the George Mason University Data Stewardship Policy #1114 regarding the transfer, use, and archiving of sensitive data;
- Inform personnel of potential hazards associated with MRI research and provide access to the MRI Policies and Procedures Manual; and
- Follow additional MRI Operator responsibilities as outlined below.

2.13 MRI Operators

It is the responsibility of all MRI Operators to conduct MRI research in a manner that will not adversely impact themselves, other personnel, the surrounding community, or the environment. Specific responsibilities of MRI Operators are to:

- Be familiar with the contents of this manual;
- Maintain appropriate training for their designated operator level;
- Limit operations within the MRI Suite in accordance with their designated operator level;
- Report incidents, accidents, and near-miss events occurring within the MRI Suite to their supervisor and the MRI Safety Manager;
- Follow all policies and procedures for MRI safety and operations and human subjects research;
- Be knowledgeable of the following:
- Suite-specific emergency procedures, contact information, evacuation procedures;

- Suite-specific procedures for managing participants, operating the scanner, recordkeeping, data management, housekeeping, and maintenance reporting;
- Location, use, storage, and maintenance of personal protective equipment; and
- Access restrictions and the need to challenge unknown persons entering the laboratory.

2.14 Neuroradiologist

It is the responsibility of the neuroradiologist to review all scans of research participants for incidental findings and to provide a report to the MRI Safety Manager who will relay the findings to the appropriate PI. The neuroradiologist may provide immediate consultation where an apparent atypicality is identified. **These records are not releasable.**

2.15 MRI Physicist

The MRI Physicist oversees technical aspects of the magnet, including any upgrades or installation of software or hardware, serves as point of contact with Siemens regarding new sequences and C2P agreements, and coordinates with the MRI Safety Manager regarding the development of quality assurance testing to meet the needs of MRI operators. Additionally, the MRI Physicist serves as a member of the MRI Policies and Procedures Committee and the Device Implant Safety Committee.

3.0 Security and Access

Unauthorized access to the MRI Suite and scanner magnet can result in injury to those who may have conditions that are unsafe for the MR environment, damage to personal items that can be affected by the magnetic field, and damage to the scanner resulting from a ferromagnetic object being pulled into the bore of the magnet. For this reason, the MRI Suite is a *Restricted Room.*

Access to the MRI Suite is controlled by electronic swipe card access. Access to the scanner room and mechanical space is controlled by manual key access. The key to the MRI Suite (screening room, console room, scanner room, and equipment room) is not contained on the Grand Master or Master key rings for the university. Unsupervised access is restricted to those individuals certified to operate the scanner; those who may need to enter the console, equipment, or scanner rooms in the event of an incident or emergency; and authorized individuals who may need to provide access to service personnel or conduct VIP tours of the facility. No one is permitted supervised or unsupervised access without appropriate notification of the potential risks associated with the magnet. Keys and electronic access to the MRI Suite must be kept in a secure location and may not be shared or loaned to other personnel.

For research study, there must be two operators present at all times while the magnet is in use. For scanning human research participants, both operators must have current CPR training.

3.1 Operator Access

The five operator levels outlined below define access and scanning privileges for the MRI Suite. Personnel who wish to work in the MRI Suite must be involved in an approved MRI research study and meet all of the eligibility and training requirements for the operator level they wish to attain. Badges will be issued indicating an individual's operator level, including a badge for a person "in training." No one should be in the MRI Suite without a badge, unless they are a research participant or a visitor. Personnel certified at Levels 2, 4, and 5 will be given electronic access to the MRI Suite and will have access to the key for the scanner and mechanical room. All operators who scan research participants or who assist in the scanning of research participants must hold current CPR certification.

- **Level 1:** At this level, personnel are permitted supervised access to the MRI Suite. Level 1 operators may not operate the scanner, but may observe and assist another operator during a scan. PI, postdoctoral fellows, undergraduate students and graduate students are eligible to become Level 1 operators. To obtain Level 1 certification, personnel must:
    - Successfully complete the *MRI Safety Training* seminar;
    - Undergo a safety screening conducted by the MRI Safety Manager and be approved for safe entry into the MRI Suite;
    - Complete annual refresher training thereafter; and
    - To serve as second operator for scans of research participants, hold current CPR certification.

- **Level 1+:** At this level, personnel are permitted supervised access to the MRI Suite. Level 1+ operators may not operate the scanner, but may observe and assist another operator during a scan. PI, postdoctoral fellows, undergraduate students and graduate students are eligible to become Level 1+ operators. To obtain Level 1+ certification, personnel must:
    - Meet all requirements for Level I training; and
    - Hold current CPR certification.

- **Level 2:** At this level, personnel are permitted unsupervised access to the MRI Suite to conduct scans of inanimate objects or phantoms. They may not operate the scanner for scans of research participants, but may observe or assist another operator during these scans. PI, postdoctoral fellows, and graduate students are eligible to become Level 2 operators. To obtain Level 2 certification, personnel must:
    - Meet all requirements for Level I training;
    - Complete an approved undergraduate level (or higher) course in MRI physics or related area or achieve an equivalent level of knowledge of MR physics;
    - Pass the *MRI Basics* exam administered by the MRI Safety Manager;
    - Successfully complete Scanner Operation Training;
    - Complete at minimum of 10 hours of supervised scanning of inanimate objects or phantoms at George Mason University, or present a letter from an institution documenting at least 20 hours of comparable independent scan time completed at that institution;
    - Pass a *Level 2 Proficiency Practicum* administered by the MRI Safety Manager; and
    - Complete annual refresher training thereafter.

- **Level 3:** In addition to Level 2 privileges, a Level 3 operator is also permitted to conduct scans of research participants under supervision of a Level 4 or Level 5 Operator. They may not conduct scans of research participants without a Level 4 or Level 5 operator present. PI, postdoctoral fellows, and graduate students are eligible to become Level 3 Operators. To obtain Level 3 certification, personnel must:
    - Meet all requirements for Level 2 training;
    - Complete a minimum of 10 hours of supervised scanning of human research participants at George Mason University, or present a letter from an institution documenting at least 20 hours of independent scan time of humans completed at the institution;
    - Pass a *Level 3 Proficiency Practicum* administered by the MRI Safety Manager;
    - Hold current CPR certification; and
    - Complete annual refresher training thereafter.

- **Level 4:** At this level, personnel are permitted to scan human research participants and may serve as a supervisor for Level 1, Level 1+, 2, and 3 operators and trainees. PI and postdoctoral fellows are eligible to become Level 4 operators. They may conduct scans of research participants without a Level 5 present. To obtain Level 4 certification, personnel must:

- Meet all requirements for Level 3 training;
- Complete 5 additional supervised scan hours (Human);
- Complete the MRI Safety & Ethics reading requirement (NIMH article);
- Pass the Final Review Checklist (Part 1) and Quiz (Part 2) administered by the MRI Safety Manager;
- Review the Implant PowerPoint Reference Guide;
- Sign the Level 4 Performance Certification form;
- Hold current CPR certification; and
- Complete annual refresher training thereafter.

- **Level 5:** Personnel at this level are ARRT-certified MRI Technologists. In addition to operating the scanner, Level 5 operators are responsible for overseeing technical operations within the MRI Suite, troubleshooting issues, and requesting service for the instrument as needed. Level 5 operators may supervise a Level 2, 3, or 4 Operator while training, if needed. To obtain level 5 certification, personnel must:
  - Follow all certification requirements as indicated by ARRT;
  - Maintain annual certification requirements; and
  - Hold current CPR certifications.

3.1.1 Limited Level Certifications

Limited level certifications are available for those who wish to obtain training on the MRI console but may not enter the MRI scanner room due to a physical limitation or a metallic implant within their body. A limited level operator would include responsibility for everything except for what happens in the scanner room. Levels 1-3 are able to achieve Limited Level status. There is no Limited Level 4 due to the responsibilities at this level.

If a limited level operator wishes to be present for scanning, a third fully trained operator must be available should an emergency situation arise.

3.2 Visitors and Tour Groups

Visitors who wish to tour the MRI Suite must be escorted by appropriately-trained personnel. Prior to entry into the console room, visitors must be briefed regarding hazards associated with the MRI and must sign the Krasnow MRI Visitor Safety Screening Form. Visitors may not enter the scanner room. At no time should a visitor be left unattended while in the MRI Suite.

To protect the privacy of research participants and to limit the potential distractions for operators, tours should be conducted when the scanner is not in use. If a tour is conducted during a participant scan, the participant must give permission for the tour in writing. All forms must be given to the MRI Safety Manager.

3.2.1 Visitors and Professors Class Sessions

If a professor wishes to conduct a session as part of a class demonstration, the session must be scheduled with the MRI Safety Manager and all students must be prescreened by the MRI Safety

Manager prior to the session taking place. A short 10-minute session must be given by the MRI Safety Manager prior to entrance of the class to provide a limited scope of MRI safety training. If the professor has included this in a prior class, this limited safety training may be waived at the discretion of the MRI Safety Manager. Students that are pregnant must follow the *MRI Guidelines for Pregnant Staff and Researchers*.

3.3 Research Participants

Research participants must be escorted throughout the MRI Suite at all times by a qualified operator and may never be left unattended. Research participants are escorted into the scanner room by a Level 4 or Level 5 operator.

3.4 Restricted Access for Ancillary Personnel

The MRI Suite is a restricted area. Housekeeping staff and maintenance personnel are not permitted to enter the MRI Suite. Trash is placed in the hallway for pickup. Light bulb changes, mopping, and other housekeeping duties are performed by the MRI Technologist. Trained service contractors are escorted while conducting working in the suite.

3.4.1 Magnetic Resonance Imaging (MRI) Guidelines for Pregnant Staff and Researchers

For safety reasons, women who are pregnant will not be scanned as part of research protocols nor will they be eligible take part in safety training. If they wish to be present for a class demonstration in the MRI console room, they must remain at the doorway of the corridor and the MRI suite.

3.4.2 Magnetic Resonance Imaging (MRI) Guidelines for Minors

Access to the MRI is restricted for individuals under the age of 18. Minors may attend Basic MRI Safety Training classroom session, but are not allowed in the MRI Scanner Suite to serve as an operator or to observe a scanning session.

3.4.3 Volunteer Adult Research Assistants (Nonstudents)

Research assistants who are volunteering in a PI's lab and are not enrolled as students at George Mason University may be eligible for MRI Operator Training. Volunteer adults are permitted to obtain training up to and including Level 3. If they have a PhD, they may be eligible to obtain a Level 4 status.

4.0 Training

Personnel receive training in MRI safety and operations, commensurate with their role and the duties they perform. It is the responsibility of each person to obtain the necessary training and to maintain proper training certification. Training requirements for the MRI Suite are determined by the MRI Policies and Procedures Committee, with final approval from the Director of Laboratory Safety/Environmental Compliance. The training program is overseen by the MRI Safety Manager who is responsible for providing training, administering proficiency exams and practicum, and maintaining training documentation. The following is a list of training offered by the Krasnow MRI Facility.

4.1 Magnetic Resonance Imaging (MRI) Operator Training

Five MRI operator levels are described in Section 3.1, Operator Access. Each of these levels has a distinct set of user privileges and, therefore, a distinct set of training requirements. Table 1 summarizes training requirements for Operator Levels 1, 2, and 3. Level 4 training requirements are currently under development; and Level 5 requirements are set by the ARRT.

Table 1. Eligibility and Training Requirements for Operator Levels 1, 2, and 3

MRI TRAINING & OPERATOR CATEGORIES	TECHNICAL MRI SCANS	HUMAN PARTICIPANT MRI SCAN
Level 1	**X**	Ineligible
Level 1+	**X**	
Level 2	**X**	

ELIGIBILITY AND TRAINING REQUIREMENTS FOR MRI OPERATOR LEVELS 1-2			
TRAINING LEVEL CRITERIA	**LEVEL 1**	**LEVEL 1+**	**LEVEL 2**
User privileges at this designated level	N/A	May serve as a partner for a Level 3, 4, or 5	Scanner for inanimate objects or phantoms with a Level 3, 4, or 5 as a partner
Operator Eligibility	Faculty, Post Doc, Undergrad & Grad Students of approved MRI study	Faculty, Post Doc, Undergrad & Grad Students of approved MRI study	Faculty/PDocs/ Graduate Students only
Annual Safety Screening Completion	Required	Required	Required
MRI Safety Training (Initial)	Required	Required	Required
MRI Safety Training (Annual Refresher)	Required	Required	Required

ELIGIBILITY AND TRAINING REQUIREMENTS FOR MRI OPERATOR LEVELS 1-2			
TRAINING LEVEL CRITERIA	**LEVEL 1**	**LEVEL 1+**	**LEVEL 2**
# of Completed Mason supervised scan hours **(Phantom)**	N/A	N/A	10 hours or Institutional letter documenting 20+ independent hours of scan time
Level Specific Training Proficiency Practicum	N/A	N/A	Required Annually
MRI Knowledge Requirement	N/A	N/A	Complete undergraduate level (or higher) course in MRI physics or related area, or an equivalent level of MRI basics exam
CPR Training & Certification	N/A	Required (to partner with Level 3,4, or 5 operator)	N/A

MRI TRAINING & OPERATOR CATEGORIES	TECHNICAL MRI SCANS	HUMAN PARTICIPANT MRI SCAN
Level 3	Completion of levels 1 & 2 required	**X**
Level 4		**X**
Level 5 Technologist	**X**	**X**

ELIGIBILITY AND TRAINING REQUIREMENTS FOR MRI OPERATOR LEVELS 3-5			
TRAINING LEVEL CRITERIA	**LEVEL 3**	**LEVEL 4**	**LEVEL 5**
User privileges at this designated level	Scanner of human participants with a Level 4 or 5 Operator as a partner	Full scanning privileges with a Level1+, 3,4,5 partner	Full scanning privileges with a Level1+, 3,4,5 partner
Operator Eligibility	Faculty/PDocs/ Grad student only	Faculty or PDocs only	ARRT Technologist only
Safety Screening Completion	Required	Required	Required
MRI Safety Training (Initial)	Required	Required	Required

ELIGIBILITY AND TRAINING REQUIREMENTS FOR MRI OPERATOR LEVELS 3-5			
TRAINING LEVEL CRITERIA	**LEVEL 3**	**LEVEL 4**	**LEVEL 5**
MRI Safety Training (Refresher)	Required	Required	Required
# of Completed Mason supervised scan hours **(Phantom)**	5 hours or Institutional letter documenting 20+ independent hours of scan time	If scanning phantoms, must meet Level 2 requirements	N/A
# of Completed Mason supervised scan hours **(Human)**	10 hours or Institutional letter documenting 20+ independent hours of scan time + 5 hours	5 hours	N/A
Level Specific Training Proficiency Practicum	Required Annually	Required Annually	N/A
MRI Knowledge Requirement	Complete undergraduate level (or higher) course in MRI physics or related area, or an equivalent level of MRI basics exam	Complete an MRI physics course, or an equivalent level of MRI basics exam, or teach an MRI related class	24 MRI technologist CEU every 2 years
Current CPR Training & Certification	Required	Required	Required
MRI Safety & Ethics Reading (NIMH)	N/A	Required	N/A
Implant Lecture	N/A	Required – Completion of Performance Certification form	N/A

4.1.1 Magnetic Resonance Imaging (MRI) Safety Training

This training is required for personnel wishing to be certified as MRI operators. The course and exam are offered on a regular basis by the MRI Safety Manager and provides an understanding of MRI hazards, safety policies and procedures for the MRI Suite, general operating procedures, and emergency response within the MRI Suite. Individuals may attend MRI Safety Training who are part of a class involving the study of MRI, or training to do phantom studies.

4.1.2 Safety Screening Seminar

This seminar provides an introduction to the MRI Safety Screening form, outlines techniques for conducting a thorough screening, and provides information about medical devices and implants and MR compatibility. The seminar is recommended for all personnel who conduct safety screenings for MRI research.

4.1.3 MRI Basics Exam

Upon completion of an undergraduate course in MRI physics (or other approved area) or after demonstrating an equivalent level of knowledge of MRI physics, a trainee is eligible to take the *MRI Basics Exam* to demonstrate their knowledge and understanding of the principles of MRI. This exam is developed by course instructors and is administered by the MRI Physicist.

4.1.4 Scanner Operation Training

Prior to initiating supervised scan time, Level 2, 3, and 4 trainees must be trained on Allegra operations. They must attend a lecture on Allegra operations and a hands-on scanner orientation session offered by the MRI Safety Manager. This lecture and orientation will include a step-by-step walk-through of operations of the scanner, review specific procedures for incident and emergency response; and for those working with research participants, techniques for managing participants before, during, and after the scan.

4.1.5 Supervised Scan Time

Upon completion of Scanner Operation Training, a Trainee is eligible for supervised scan time under the direct supervision of either an MRI Technologist or a PI with Level 2, 3, or 4 operator status. During this time, the trainee receives hands-on training from the supervisor until they are able to confidently operate the scanner. For Level 2 trainees, a minimum of 10 hours scanning phantoms or inanimate objects is required. For Level 3 trainees, a minimum of five hours scanning phantoms or inanimate objects is required followed by a minimum of 10 hours scanning research participants. Trainees who require additional hours of scan time prior to taking the proficiency practicum are encouraged to continue to scan with supervision until they are proficient and the supervisor is confident in their abilities to operate the scanner independently. However, trainees may not take the proficiency practicum before they have completed the minimum number of supervised scanning hours.

4.1.6 Proficiency Practicum

Trainees who have completed supervised scan time or provided documentation of scan time at their previous institution are eligible to take the proficiency practicum for the level of access they wish to attain. The practicum is administered by the MRI Safety Manager and tests the trainee's competency, ability to operate the scanner independently, and ability to respond appropriately to emergencies.

If a trainee fails the proficiency practicum, they may require additional supervised scan time before retaking the practicum. It should be noted that some individuals may not have the appropriate skills or ability to operate the scanner independently. While every effort will be made to provide adequate training for all trainees, operator status will not be given to individuals who do not demonstrate competency and proficiency in scanner operations and safety. Instances where trainees feel they were unjustly denied operator status will be reviewed by the Director of Laboratory Safety/Environmental Compliance and assessed on a case-by-case basis.

4.1.7 Cardiopulmonary Resuscitation (CPR) Training and Certification

All operators who will serve as either the primary or secondary operator for scans of research participants must have current CPR certification through either the Red Cross or the American Heart Association. This training is not offered by George Mason University. A copy of CPR certification must be provided to the MRI Safety Manager.

4.1.8 Laboratory Safety Awareness Training

University Police and Facilities Management personnel, including housekeeping staff, are provided *Laboratory Safety Awareness Training*. This training offers participants a fundamental overview of laboratory hazards, hazard identification, and emergency response. A brief overview to the hazards associated with MRI is included as part of this training.

4.1.9 MRI Safety Awareness Training

This training, offered primarily to occupants of the Krasnow Institute, provides general awareness of the MRI Suite and illustrates why access to the MRI Suite is tightly controlled and monitored.

5.0 Magnetic Resonance Imaging (MRI) Safety Screening

All individuals, including operators, researchers, staff, students, research participants, and visitors must be screened prior to entering the MRI Suite. A standardized form (*Krasnow MRI Safety Screening Form*) is used to evaluate the safety of each person before that person is permitted in the MRI Suite.

5.1 Screening Researchers, Staff, and Students

Operators, researchers, staff, and students who intend to enter the MRI Suite are screened by the MRI Safety Manager prior to attending *MRI Safety Training*. Screening for these individuals must be updated on an annual basis. Additionally, it is the responsibility of these individuals to notify the MRI Safety Manager and the MRI Technologist if a contraindication (such as pregnancy, surgery, or injuries involving ferromagnetic material) that could prevent them from entering the scanner should arise.

5.2 Safety Screening of Visitors

George Mason University recognizes two types of visitors to the MRI Suite: family members of research participants who will enter the scanner room with the participant, and individuals who come to view or observe as part of a guided tour. Visitors who accompany research participants into the scanner room must pass the safety screening conducted using the *Krasnow MRI Safety Screening Form*.

The *Krasnow MRI Visitor Form* is used for visitors who are part of a guided tour. For safety reasons, these individuals are limited to the console room unless additional safety screening is performed. Additional information regarding guided tours is provided in Section 3.0 Security and Access.

5.2.1 Screening Minors as a Participant

Anyone under the age of 18 who requires a screening must have a parent or legal guardian present at time of screening and signature required on the screening form.

5.3 Safety Screening of Research Participants

Research participants are screened a minimum of two times. Safety screening may be performed in person or over the phone. Both safety screens must be completed every time a research participant prepares to undergo an MRI scan.

The preliminary screening is conducted prior to scheduling the participant for a scan. The individual conducting the screening must be on a current IRB protocol and have completed IRB-approved research ethics training and attended the MRI Screening seminar.

If the research participant has any conditions listed in Section 5.4, Exclusionary Criteria, they are automatically excluded from participating in an MRI study at George Mason University. The PI

may also decide to exclude participants that have items listed in Section 5.7, Items that May Affect Image Quality, or if the participant experiences claustrophobia or has a condition that makes it difficult for the participant to lie still for the duration of the scan.

If the research participant has had any type of surgery, or has any of the implants or devices listed in Section 5.5, Criteria that May Exclude Research Participants, the Device and Implant Safety Committee must make a recommendation to approve or exclude the research participant. All implants and devices, whether MR safe or not, must be documented on the screening form, and the following information must be collected for each device or implant:

- Type;
- Manufacturer;
- Make or model; and
- Serial number.

For surgical implants, this information may be provided in a Material Identification Card. If the research participant is willing to provide a surgical report, this information may also be collected. Information must be sufficient to verify the compatibility of the implant with the MR environment. The PI is responsible for forwarding the necessary information to the Device and Implant Safety Committee for review.

The second screening is conducted by the MRI Technologist within 48 hours of the participant's scheduled scan time. The MRI Technologist may cancel or postpone a scan if the research participant's second screening raises suspicion about the suitability of the participant for the MRI environment. The MRI Safety Manager maintains a file of the second screening of each participant.

5.3.1 Second Screening Performed by an MRI Physicist

In the absence of the technologist for a final screening just prior to scanning, any of the following may be acceptable:

- The MRI Physicist may perform a final screening if the participant has been scanned at George Mason University within the last three months and a copy of the previous screening sheet is made available for review (comparison).
- The technologist may screen the participant within 48 hours of the scan time and provide the screening sheet to the Level 4 Operator for final review at the time of scanning (provided a T2 axial sequence for clinical purposes has been obtained within the last 12 months at George Mason University).

5.3.2 Pregnancy and Female Participants

Even though there are no known effects of MRI on the unborn fetus, there is no data on the effects on fetal development. Therefore, participants who think that they might be pregnant cannot be scanned.

5.4 Exclusionary Criteria

Participants with any of the following implants or conditions are excluded from participating in MRI studies at the Krasnow Institute:

- Metal in the eyes or an injury to the eyes involving a metal object or fragment (such as metallic slivers, shavings or a foreign body);
- A pacemaker or implanted cardioverter defibrillator;
- Eye implants (prosthesis, retinal tack, eyelid wire or spring);
- Electronic implant or device;
- Magnetically-activated implant or device;
- Internal electrodes or wires;
- Tissue expander (e.g., to expand tissue prior to a breast implant. Breast implants themselves are not exclusionary;)
- Shunts (spinal or intraventricular);
- Vascular access port and or catheter;
- Neurostimulator system, spinal cord stimulator, bone growth/bone fusion stimulator;
- Aneurysm clips;
- Any type of nonremovable pump (pain, drug infusion, insulin, etc.);
- Tattoos above the neck to include permanent cosmetics (e.g., eye or lip liner, etc.);
- Ear surgeries, implants (cochlear and otologic), stapes, prosthetic ear bone;
- For females, IUD;
- For males, penile implant;
- Any implant labeled MR unsafe;
- Any implant labeled MR conditional that is not deemed safe at 3T;
- Any implant for which clear and unambiguous documentation cannot be provided to verify the implant is MR safe at 3T; or
- Pregnant females.

5.5 Criteria that May Exclude Research Participants

Clearance by the Device and Implant Safety Committee is required for research participants with any of the following conditions:

- History of surgical procedures that may or may not contain implants;
- Injury involving an object or foreign body, such as a BB, bullet, shrapnel, or shard of metal;
- Joint replacement (hip, knee, etc.);
- Bone/joint pin, screw, nail, wire, plate, etc.;
- Surgical staples, clips, or metallic sutures;
- Artificial limb;
- Wire mesh implant;
- Heart valve prosthesis;
- Insulin pump;

- Metallic stents, filters, or coils;
- Other implants not listed above;
- A history of claustrophobia; or
- Medication patches (nicotine, nitroglycerine, contraceptive, pain).

5.6 Clearance Procedure for Devices and Implants

Research participants with implants or devices will not be permitted to participate in an MRI study at the Krasnow Institute unless clear and unambiguous documentation verifies that the implant is MR safe at 3T. The PI is responsible for forwarding the preliminary screening form and required documentation to the Device and Implant Safety Committee for review. The committee will recommend whether to approve or exclude a research participant. If the committee recommends that the device or implant is MR safe, the PI makes the final decision to include the participant in the study. For a device to be recommended as safe for a scan, the following criteria must be met:

- Clear and unambiguous documentation exists verifying that the device or implant is MR safe at 3T.
- The implant is rated as MR safe at 3T according to the *Reference Manual for Magnetic Resonance Safety, Implants and Devices*, by Frank G. Shellock, PhD, or www.mrisafety.com.
- A medical professional certifies that the implant is safe.

5.7 Items that May Affect Image Quality

Certain types of dental work can cause artifacts that reduce image quality. For this reason, all removable dental work should be removed prior to the scan. Full metal braces cause significant image distortion, particularly in gradient echo imaging. For participants with permanent retainer on the lower front teeth, permanent bridgework, crowns, or nonremovable partials, image quality should be evaluated after the first two sequences of a study are obtained to determine if the data is usable.

Certain types of hair treatments (e.g., weaves, braids, extensions) can also cause artifacts due to the presence of small metallic clips.

5.8 Removable Items

The following items must be removed before entering into the MRI Suite. Any or all of the following items may result in either injury or damage to the item or the scanner.

- Insulin pumps (An exception can be made when the pump is known to be MR compatible. In this case, the outer battery pack must be removed before entering the scanning room.);
- Prosthesis;
- Medication/birth control/pain patches. These patches may have a foil backing and can cause a burn on a participant's skin if placed in the scanner. The subject will need to

contact his/her physician before agreeing to a scanning time to see if the patch can be removed for the duration of the scanning period. The decision to remove these patches is not to be made by the researcher/operator or MRI Technologist;

- Diaphragm and pessary (females);
- Body piercing jewelry/rings/necklaces. Any jewelry made of nonferrous or ferrous metal that is in the form of a loop can cause a burn due to the possibility that it may induce a current;
- Hearing aids. These contain a battery and may damage the hearing aid beyond repair;
- Colored contact lenses. Colored contacts worn in place of glasses may contain metallic dyes depending on the color of the lenses. There may be a slight risk that this could cause heating and irritation of the eyes while scanning. For this reason colored contacts must be removed prior to scanning. Clear contacts are acceptable and pose no risk;
- Eyeglasses. Eyeglasses must be removed prior to entering the scanner room. Metal components are almost always contained in the hinges of glasses and would cause an artifact even if the components were not made of ferrous material. Injury to the participant could occur and the glasses could be destroyed if they became attracted to inside of the bore of the magnet;
- Dentures, partial plates, and nonpermanent retainers. All dental work that is removable should be removed. All of the above items listed are to be removed even if no metal is visibly seen to ensure no artifact would be present on the images; and
- Clothing made with metallic components. Participants may arrive with clothing made with metallic threads and/or metallic decorative artwork. This type of fabric may have a tendency to heat, smoke or potentially cause a burn to the participant if exposed to the skin. Such articles of clothing need to be removed before a participant is placed into the magnet. If the article of clothing is the participant's primary shirt or sweater, Krasnow MRI provides laundered sweatshirts for the participant located in the screening room to wear for the duration of the scan.

6.0 Project Review and Approval

All proposed research for the MRI Suite must be approved by NICKI prior to commencement of work. Additionally, all research involving research participants must be approved by the Institutional Review Board (IRB) prior to commencement of work. All research involving research participants proposed by non-George Mason University investigators must be approved by their IRB before applying to the George Mason University IRB.

6.1 Neuroimaging Core of the Krasnow Institute of Advanced Study (NICKI) Approval

NICKI serves as a scientific governing board for the Krasnow Institute MRI scanner. PIs who wish to use the scanner are required to provide information regarding their institution, project, IRB approvals, and funding status to NICKI. An online application form is available at www.krasnow.gmu.edu/nicki/research.html. Before commencement of the work, all personnel must complete required training and safety screening to become an MRI Operator.

6.2 Institutional Review Board (IRB) Approval

The IRB reviews all research projects involving research participants prior to initiation of the project. The *Human Subjects Application Form* and instructions are available through the online protocol management system. Details are available here: http://oria.gmu.edu/research-with-humans-or-animals/institutional-review-board/. Investigators from outside George Mason University must have NICKI approval and approval by their IRB before applying to George Mason University IRB.

PI must make sure that the IRB protocols list all personnel who will be conducting MRI research and that each person who will conduct research has successfully completed IRB-required *CITI Training*.

6.3 Validity Testing

Validity testing is defined as testing a task and/or sequence in the scanner to determine whether the proposed work is feasible before developing a pilot study or finalizing a proposed study for IRB approval. The nature of validity testing may require a researcher to be scanned. Because the scan itself will not be used as scientific data, and because participants will not be scanned, IRB approval is not required. All individuals who are scanned as part of validity testing must sign a *MRI Nonparticipant Consent Form* prior to the scan. The signed consent form will be kept on file by the PI and a copy will be given to the individual.

6.4 Pilot Experimentation

Applications for pilot experiments should follow the application steps listed on the NICKI website and must include results from the behavioral study if the experiment is for functional MRI and/or provide justification for structural applications if the study is MRI only.

Pilot experiments that are accepted will be permitted a session with the MRI Technologist to work out their scanning protocol and to test with a phantom. Pilot functional MRI experiments will be permitted to run 4 (if the study is on one population) and 8 (if the study includes more than one population of interest) participants to collect data for the purposes of validating the task and protocol and collecting data for grant submission purposes. (Unfunded pilot studies will be charged a nominal rate - see website for fees and rates: http://krasnow.gmu.edu/nicki/research.html). Pilot structural experiments will be permitted three participants for piloting.

7.0 Scheduling

Scheduling for the MRI scanner is coordinated by the MRI Safety Manager using a online calendar. The calendar can be viewed at http://krasnow.gmu.edu/nicki/calendar.html. To reserve scanner time, MRI Users may contact the MRI Safety Manager by phone, 703-993-1894, or email at mmoe2@gmu.edu. The MRI Safety Manager will schedule the appropriate amount of time for the study. Thirty minutes will be added to each scanning slot to allow for delays in participant's arrival, computer task setup, and room turnaround. A confirmation email will be sent to the PI or MRI User specifying the date and time of the scan. Reminder emails will not be sent. Evening and weekend hours are available upon request.

The MRI Safety Manager should be notified as far in advance as possible of cancellations or the need to reschedule so that the calendar can be updated to reflect available scan times.

If a PI or MRI Operator wishes to secure an entire day on a consistent basis (e.g., one day specified each week), the PI or MRI Operator must confirm and/or verify need within 48 hours of the need; otherwise the time will become available for general use. Names of participants will not be listed on the schedule, only the PI's last name and the name of the study.

8.0 Rules of the Neuroimaging Core of the Krasnow Institute of Advanced Study (MRI) Suite

The MRI Suite is a shared resource. Any action that inhibits or has the potential to inhibit the ability to utilize these resources will be considered a policy violation. Operators are expected to use good judgment in their use of the MRI Suite, and to follow the policies and procedures put forth in this manual and in the standard operating procedures (SOP) for the MRI Suite.

The following rules must be followed by all operators in the MRI Suite:

- No follow-up scanning of clinical sequences permitted unless it is specifically designated within a PI's protocol.
- Doors to the MRI Suite (console, scanner, and equipment rooms) must be kept closed and secured at all times.
- No eating, drinking, use of tobacco products, or storage of food and beverages is permitted in the MRI Suite.
- Access to the MRI Suite is restricted to authorized individuals.
- Before entering the scanner room, personnel must remove the following items: hearing aids, keys, beeper, cell phone, hairclips, barrettes, pins, jewelry, watch, wallets, credit cards, bank cards, pens, pocket knife, nail clips, or any other objects that contain ferromagnetic material or that may be damaged by the magnetic field.
- Any equipment to be used in the scanner room must be approved by the MRI Safety Manager and MRI Physicist. All equipment must be tested for ferromagnetic properties with a handheld magnet before being brought into the scanner room.
- Two appropriately-trained MRI operators must be present to operate the MR scanner.
- For scans involving research participants, both operators must hold current CPR certification.
- The MRI Operator has the authority to stop MRI procedures deemed by them to be unsafe.
- For scans involving human research participants:
    - Ensure participants sign a consent form before entering the scanner, and remove all items as listed in Section 5.8 and items that are not MR-compatible (keys, cards with magnetic strips, etc) according to SOP. The screening room should be used to secure participants' personal belongings and other removable items.
    - Instruct participants not to cross their arms or legs or in any way form a closed loop with their extremities. This will reduce or avoid peripheral nerve stimulation.
    - Instruct participants on how and when to use the emergency squeeze ball.
    - Instruct participants to inform the operator if they experience the following: excessive perspiration, rapid heart rate, difficulty breathing, tightness of chest, pain or discomfort to including warming of the skin, muscle tingling, etc.
    - Provide hearing protection to the research participants and any visitor who will remain in the scanner room during the scan, and instruct them on its proper use, ensuring that hearing protection is properly placed.

- Maintain verbal contact with the research participant. Immediately investigate a research participant who does not respond verbally to ensure their well being.
- Stop the scan if an individual becomes ill or injured. Remove the participant from the magnetic environment immediately and follow incident response procedures. Provide a reportable information/incidents form to the IRB within five business days.
- Properly clean all surfaces that have come into contact with a research participant before the next MRI scan is conducted.
- Report all incidents and near-incidents, including equipment malfunctions, projectile accidents, security or safety breaches, or injury to personnel or research participants, to the PI and MRI Safety Manager.

8.1 Prox Card Access to the Neuroimaging Core of the Krasnow Institute of Advanced Study (MRI) Suite

Access to the MRI scanner suite will be given to Level 4 candidates once the MRI Policy and Procedures committee has approved the candidate based on the MRI Safety Manager's recommendation. The MRI Safety Manager will fill out the necessary paperwork to activate the Prox card. Once the card has been activated it will be tested and given to the recipient by the MRI Safety Manager. A log of all those having Prox card access will be kept on the EHS shared drive.

9.0 Housekeeping and Maintenance

The Director of the Krasnow Institute provides resources to maintain all necessary service contracts for the MRI Suite. The MRI Safety Manager oversees scheduling of service and maintenance. Preventive maintenance on the scanner is conducted quarterly. Cryogenic liquid used to cool the magnet is replenished quarterly. The chiller and HVAC system are serviced quarterly.

Housekeeping duties for the MRI Suite (sweeping and mopping floors, and cleaning) are performed by the MRI Technologists. Floors are swept and mopped weekly. In addition, the scanner table is cleaned after every use. Blankets for research participants' comfort are laundered by George Mason University Housekeeping. The Assistant Housekeeping Manager can be contacted at 703-993-3818 concerning laundering services.

10.0 Considerations for Research Participants

Research participants traveling to the Krasnow Institute should be provided directions to the campus and basic information regarding the following to facilitate their visit to George Mason University. A map and directions are available at http://www.gmu.edu/resources/welcome/Directions-to-GMU.html.

- **Parking**: Limited metered parking is available across Shenandoah River Lane or in the campus parking decks. Additionally, PI may purchase and provide parking passes for research participants.
- **Upon Arrival**: Participants should be instructed to wait in the lobby of Krasnow Institute until they can be escorted to the MRI Suite. An investigator should meet the participant in the lobby to escort them through the building.
- **Arrival Time**: Research participants should be instructed to arrive with sufficient time to complete safety screening and to prepare for the scan. The amount of time required may depend upon the conditions of each particular study. If the participant is running late, consideration must be made for any studies scheduled after that participant. In some cases, the participant may need to be rescheduled.
- **Confidentiality**: Policies regarding privacy for research participants are clearly outlined by the IRB; and it is the responsibility of the PI to ensure these policies are followed. Names of research participants are not listed in the imaging data acquired by the scanner.

Each investigator is encouraged to examine data collections to ensure that the contents of the collection do not violate explicit or implicit pledges of confidentiality given to research participants. Data items that could be used as identifiers should be removed, masked, or collapsed (according to the Health Insurance Portability and Accountability Act of 1996) unless the investigator has a limited data set agreement in place which provides for sharing of protected information. Investigators choosing to share limited data are encouraged to do so under a *Data Use Agreement*.

11.0 Incidental Findings

As a service to research participants, George Mason University sends structural scans to a consulting neuroradiologist for review, and relays any findings deemed reportable in the view of the neuroradiologist to the research participants. For this purpose, a two-minute T2 weighted structural scan is run by the MRI Technologist at least once per year for each research participant, and is forwarded to the consulting neuroradiologist along with the T1 structural scans. Image data is sent to the neuroradiologist monthly, unless atypicality is observed, in which case the images are sent immediately for urgent review. The results are relayed to research participants in accordance with stipulations of the IRB and the Director of Risk Management.

12.0 Recordkeeping

Records regarding MRI safety and compliance, research participants, scans, equipment maintenance and repair, as well as usage and billing, are maintained by the MRI Safety Manager and PI overseeing research study. A list of records is outlined below.

- Training Records: EHS maintains safety and compliance training records for all personnel. The MRI Safety Manager manages these records and maintains documentation of proficiency testing and copies of CPR certification for MRI Operators.

- Screening Forms: Preliminary safety screening forms for research participants are kept on file by the PI overseeing the study. The second safety screening form for each participant is kept on file by the MRI Safety Manager. The MRI Safety Manager also maintains safety screening forms for MRI Operators, other George Mason University personnel, and visitors who enter the scanner room with research participants.

- Visitor Forms: Visitor Forms for tours of the MRI Suite are kept on file in the MRI Console Room and maintained by the MRI Safety Manager.

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

- Incidental Findings: The MRI Safety Manager maintains the MRI Incidental Findings Review forms. These forms do not contain identifying information and will follow the naming convention for scanner files. These forms are kept in a locked file cabinet in the MRI Equipment Room (Zone 3b) where only the MRI Safety Manager, MRI Technologist, and Siemens engineers have access.

- Data: The naming convention for all imaging studies will not contain any identifying information and will be listed as follows: PI Name-Name of Study-Participant#.

  Per the rules and regulations of the George Mason University IRB, it is the jurisdiction and responsibility of the PI to keep their research participant's information protected and confidential. They will retain copies of their own participant's signed informed consents and assents, MRI prescreening, and any other documentation related to participation in their study. Once imaging data has been shared with the PI, it becomes their jurisdiction and responsibility to maintain and use the data in a confidential and appropriate manner.

- Data Logs: The following logs are kept by the MRI Safety Manager and MRI Technologist:
  - 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 Siemens for maintenance and scanner errors;

- Participant archive log for the neuroradiologist;
- IP addresses, port numbers, application entry titles; and
- Participant archive log of all participants scanned.

- 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 Business Manager for the Krasnow Institute. When using the scanner, MRI Operators must record the following information:
  - Date;
  - IRB number (when appropriate) and study name or description;
  - PI overseeing the project or study;
  - Type of project or study (pilot study, research participant, phantom scanning, validation testing, etc.);
  - Participant number (when appropriate);
  - Funding or Org number; and
  - Start and end time of scanner use.

13.0 Emergency Procedures

Emergencies, by their nature, are unpredictable and unexpected events that pose a potential threat to health and safety of personnel, property, and the environment. Each emergency event will be unique and will require assessment to determine the appropriate response. The MRI Suite poses a hazard for emergency response personnel in that they cannot safely enter the suite with typical emergency response equipment. Therefore, emergency response procedures for the MRI Suite must include MR safe equipment whenever possible, and procedures for removal of injured or ill individuals from the suite by the MRI Operators. University Police receive training regarding hazards associated with the MRI Suite and are aware not to enter the suite while the magnet is operational.

This section provides general emergency procedures for the MRI Suite. Additional emergency response information for the Allegra 3T magnet is available in the MRI Console Room.

13.1 Emergency Preparation

In preparing for emergencies in the MRI Suite, MRI Operators must know the appropriate procedures for emergencies involving research participants, appropriate steps for safely shutting down the magnet, the location and use of any emergency equipment, emergency contact information, and any necessary follow-up procedures.

The required elements of emergency preparedness for the MRI Suite are:

- The *Emergency Response SOP* outlining specific response procedures are provided in the MRI Console Room, along with a list of emergency contacts.
- MRI Operators are trained on the *Emergency Response SOP* and participate in routine drills and exercises in the MRI Suite.
- A first aid kit is stocked and available in the Krasnow kitchen.
- Two MR safe fire extinguishers are located in the scanner and console rooms. A fire extinguisher is also present in the equipment room.
- A MR safe stretcher is kept in the scanner room.
- Two MRI Operators must be present for use of the scanner. For studies with research participants, both MRI Operators must hold current CPR certification.
- It is recommended that MRI Operators receive Fire Extinguisher Training (offered by EHS-Fire Safety).
- A spill supply kit is located in the console room.

13.2 Emergency Notification

When an emergency situation arises, contact University Police by dialing 911 from any George Mason University phone, or by dialing 703-993-2810. Provide the following information:

- Name and telephone number of the caller;
- Nature of the emergency (e.g., medical emergency, technical problem, fire, etc.);

- Specify that this is the Krasnow Institute MRI Suite with magnetic hazards; and
- Special considerations (e.g., hazardous gases present, people trapped, number of people injured and type of injuries, electrical hazards, property damage and access routes to the emergency).

13.3 Termination of Scanning and Participant Evacuation

MRI Operators must be prepared at all times to handle an emergency involving a research participant, and must be able to identify signs that the participant is experiencing discomfort or distress.

MRI Operators should provide the emergency squeeze ball to participants and make sure the participant is comfortable with its use. Operators must also remain in verbal contact with the participant throughout the scan.

13.3.1 Reasons for Terminating a Scan

The MRI Operator should terminate the scan when any of the following occur:

- The research participant experiences any symptoms of claustrophobia, such as increased perspiration, increased heart rate, difficulty breathing, or tightness of the chest. Most participants experiencing these symptoms will ask to be removed from the scanner. However, they may not associate the symptoms with claustrophobia.
- The participant experiences pain or discomfort, to include warming of the skin, muscle tingling, etc.
- The participant feels ill or experiences dizziness or nausea.
- The participant experiences a medical emergency or becomes unresponsive.
- Technical issues such as the following occur:
    - Power outage;
    - Fire alarm;
    - Scanner console freezes (and problem is not resolved by rebooting the scanner);
    - Head coil malfunctions;
    - Gradient errors occur;
    - Cold head is not working; or
    - Kraus chiller malfunctions.

A research participant must never be asked to remain in the magnet when experiencing discomfort or distress and should never be kept in the scanner while technical concerns are evaluated.

13.3.2 Emergency Evacuation Procedure for a Responsive Participant

If the research participant is conscious and is able to communicate, follow these steps:

- Press the STOP SCAN button.
- Move the table out of the magnet using the toggle switch.

- Lower the table down to the floor as low as possible.
- Have the participant sit up, but do not have them get up off the table right away.
- Assess the research participant.
- If the participant is experiencing a medical emergency, call 911 and follow emergency notification procedures in Section 13.2.
- If the symptoms subside and the participant feels better, the participant may be escorted from the facility, and a recommendation made to the participant for follow-up with a medical professional if the symptoms recur.

13.3.3 Emergency Evacuation for a Nonresponsive Participant

If the participant becomes unresponsive at any time during the procedure, scanning should be stopped immediately.

- Press the STOP SCAN button.
- Bring the table all the way out of the bore (do not lower the table).
- Slide the participant's head out of the coil and onto the table pad.
- Move the stretcher from against the wall next to the table.
- Roll the participant with the table pad to face the counter and cabinetry in the room and slide the white transfer board halfway under the subject and table pad.
- As one unit, slide the participant and table pad across the white board onto the stretcher. (The board is to be used as a bridge.)
- Wheel the stretcher, with the participant on it, out of the scanner room into the control room.
- Close the scanner door.
- Open the hallway door and wheel the participant out into the main corridor.
- Call 911 from a university phone and give the operator the location (Krasnow Building, lower level corridor outside Room 102) and instruct the other researcher to obtain the AED unit from the first floor.

13.4 Quench

The MRI scanner is super-cooled with liquid helium. Quench is the rapid boiling off of this liquid either intentionally or unintentionally.

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 person is pinned to the magnet and is unable to be removed from the scanner without harm.
- There is a fire in the MRI scanner, equipment, or console room.
- There is a fire in another area of the Krasnow Building and fire, smoke, or water damage is a threat to the MRI Suite.

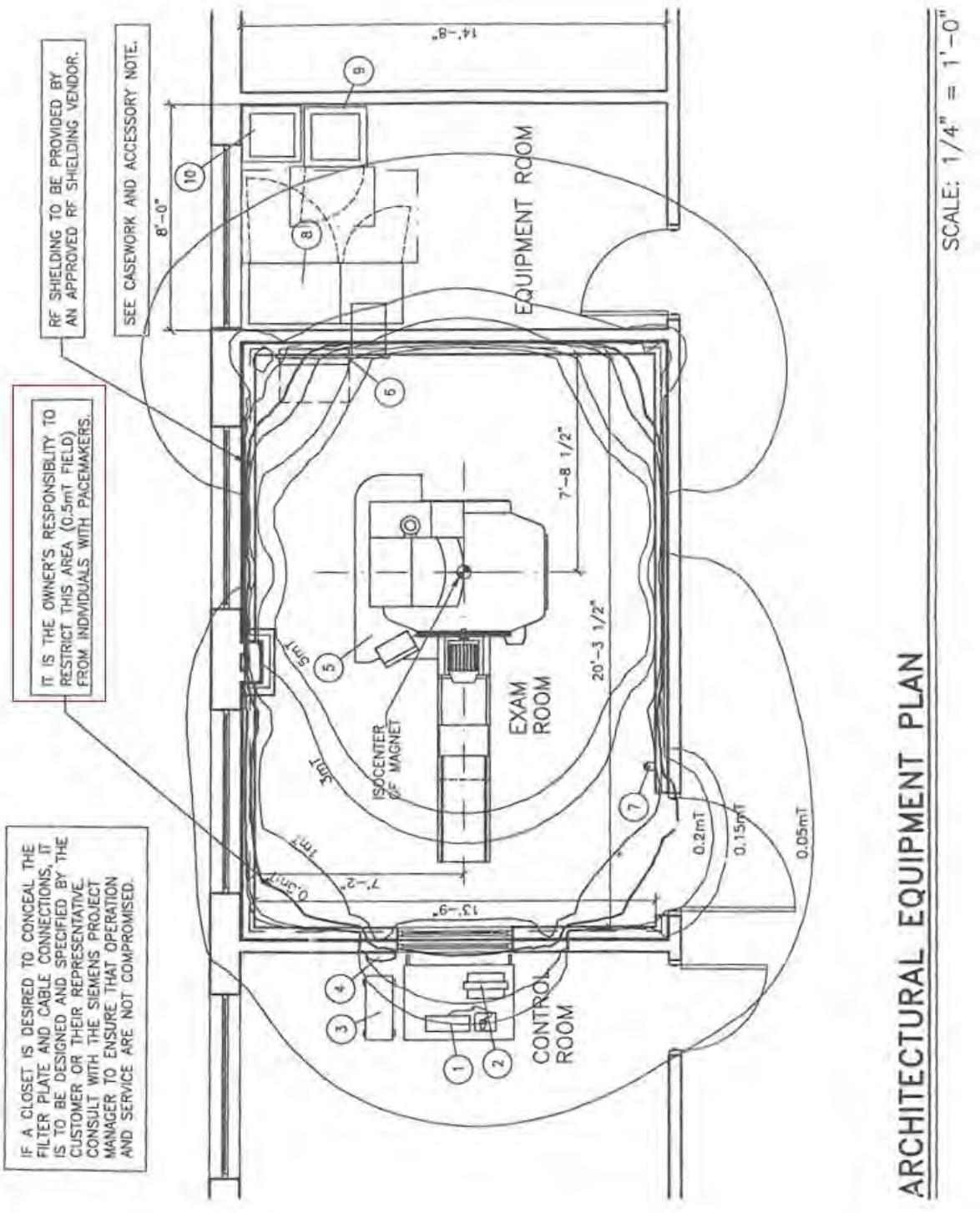
The MRI Suite is designed to exhaust gaseous helium directly outside the building. However, due to potential for displacement of oxygen and the creation of a hypoxic environment, the MRI Suite should be evacuated anytime a quench is performed.

13.5 Fire

If an electrical fire were to occur in any of the three MRI rooms console, magnet, or equipment room, two nonferrous water mist fire extinguishers are located within the MRI Suite to contain the fire. Personnel are not required to fight fires and should evacuate the building immediately in the event of a fire. University Police has the primary responsibility for managing emergencies and must be notified immediately of such situations by calling 911 from any campus phone or 703-993-2810. Employees may use fire extinguishers to fight small, incipient fires (no larger than a waste basket) only if they have been trained in the proper use of a fire extinguisher and are confident in their ability to cope with the hazards of a fire. In such cases, firefighting efforts must be terminated when it becomes obvious that there is danger from smoke, heat, or flames. If a fire occurs in the MRI Suite or the building fire alarm sounds:

- Stop the scan and remove the research participant as described in Section 13.3.2.
- If the fire is within the MRI Suite, quench the magnet so that emergency responders can safely respond to the fire.
- Have all individuals in the MRI Suite evacuate the building in a calm manner and according to the building evacuation plan. Never use elevators.
- Congregate at the predesignated assembly area for the building.
- Notify emergency response personnel if you have specific information about the fire and whether or not the magnet was quenched.

Appendix A
0.5 Gauss Line



Appendix B
Participant Screening Form

GEORGE MASON UNIVERSITY

KRASNOW MRI PARTICIPANT SAFETY SCREENING FORM (Revised 5-20-13)

Date_____/_____/_____ (MONTH) (DAY) (YEAR) Participant Number_____

Name _____ (LAST) (FIRST) (MIDDLE INITIAL)

Date of Birth_____/_____/_____ (MONTH) (DAY) (YEAR) Male Female (CIRCLE ONE) Height_____ Weight_____

Address _____ (STREET, APT #) (CITY, STATE) (ZIP CODE)

Home Telephone (____) ____ - _____ Work Telephone (____) ____ - _____ Cell Telephone (____) ____ - _____

E-mail Address _____ Principal Investigator_____

TO BE READ TO ALL PARTICIPANTS: THE MRI CONTAINS A VERY STRONG MAGNET THAT CAN ATTRACT METAL OBJECTS AND IMPAIR ELECTRONIC DEVICES. IF YOU HAVE ANY MAGNETIC OBJECTS ON OR IN YOUR BODY OR ANY ELECTRONIC DEVICES, THEY COULD BE DAMAGED OR CAUSE YOU HARM IF YOU ENTER THE SCANNER ROOM. THEREFORE, IT IS IMPORTANT THAT YOU ANSWER EACH QUESTION HONESTLY AND THOROUGHLY.

A. A PARTICIPANT WHO ANSWERS YES TO ANY OF THE FOLLOWING QUESTIONS MUST BE EXCLUDED FROM MRI STUDIES.

1. Have you ever worked with metal (grinding, fabrication, etc.), or ever had an injury to the eye involving a metallic object (e.g. metallic slivers, foreign body)? Yes No

   If yes, please describe: _____

2. Please indicate if you have any of the following:

a.	A cardiac pacemaker, implanted cardioverter defibrillator (ICD)	Yes No	i.	Vascular access port and or catheter	Yes No
b.	Eye implants (prosthesis, retinal tack, eyelid wire or spring)	Yes No	j.	Neurostimulator system, spinal cord stimulator, bone growth/bone fusion stimulator	Yes No
c.	Metal object in the brain (implant, clip, wire, etc.)	Yes No	k.	Aneurysm clips	Yes No
d.	Electronic implant, device, or microchip	Yes No	l.	Any type of nonremovable pump (pain, drug infusion, insulin, etc.)	Yes No
e.	Magnetically-activated implant or device	Yes No	m.	Tattoos on face or permanent cosmetics (e.g., eye or lip liner, etc.) or on neck or above	Yes No
f.	Internal electrodes or wires	Yes No	n.	Ear implants (cochlear,otologic,stapes,prosthetic ear bone)	Yes No
g.	Tissue expander	Yes No	o.	[For females] IUD	Yes No
h.	Shunts (spinal or intraventricular)	Yes No	p.	[For males] Penile implant	Yes No

3. [For females] Do you think you might be pregnant? Yes___ No___.

B. IF A PARTICIPANT ANSWERS YES TO ANY OF THE FOLLOWING QUESTIONS, THEY MAY NEED TO BE CLEARED BY THE PARTICIPANT SAFETY COMMITTEE.

1. Have you ever been injured by an object or foreign body, such as a BB, bullet, shrapnel, or shard of metal? Yes No
2. Have you ever been injured with metal that may still be left in your body? Yes No
   If yes, please describe: _____

3. Please indicate if you have any of the following:

a.	Joint replacement (hip, knee, etc.)	Yes No	e.	Wire mesh implant	Yes No
b.	Bone/joint pin, screw, nail, wire, plate, etc.	Yes No	f.	Heart valve prosthesis	Yes No
c.	Surgical staples, clips, or metallic sutures	Yes No	g.	Any type of insulin pump	Yes No
d.	Artificial limb	Yes No	h.	Metallic stents, filters, or coils	Yes No
			i.	Other implant:_____	Yes No

   If yes to any of the above, do you have a medical card? If yes, please circle the letter that corresponds with the item number above
   a. b. c. d. e. f. g. h. i.
   If you do have any of the above, please fill in the appropriate information below for each one:

   Make_____ Model_____ Serial # _____ Date of Implant ____/____/____ (MONTH) (DAY) (YEAR)

4. Do you experience claustrophobia? Yes No
5. Do you wear any medication patches (nicotine, nitroglycerine, contraceptive, pain)? Yes No
   If yes, is there a period of time that you normally do not wear the patch? Yes No

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C. The following questions are in regard to conditions that may affect the quality of MR images.

1. Please indicate if you currently have any of the following:
   a. Braces,permanent retainer, caps, crowns Yes No | b. Hair weaves, wig, extension and/or braids Yes No

D. BACKGROUND INFORMATION.

1. Have you ever had a prior diagnostic imaging study or examination (MRI, CT, ultrasound, X-ray, etc)? Yes No
   If yes, please list Body Part Date Facility

   MRI _____ __/__/____ _____
   Other_____ _____ __/__/____ _____

2. Have you experienced any problem related to a previous MRI examination or MR procedure? Yes No
   If yes, please describe:_____
3. Surgical History: List all prior surgeries below and their approximate dates. Include operations, arthroscopy, endoscopy, biopsies, etc.. You cannot be scanned until 90 days has elapsed following any surgery.

   _____
   _____
   _____
   _____

E. IF A PARTICIPANT ANSWERS YES TO ANY OF THE FOLLOWING, THEY ARE REQUIRED TO REMOVE THEM BEFORE ENTERING THE MRI SUITE.

Do you have any of the following?

a) Hearing aid	Yes	No	d) Colored contact lenses	Yes	No
b) Body piercing jewelry	Yes	No	e) [For females] diaphragm, cervical ring, or pessary	Yes	No
c) Removable dental work (dentures, partial plates)	Yes	No	f) Prescription eyewear	Yes	No
			If yes, can you see without them?	Yes	No

F. TO BE ASKED THE DAY OF THE SCAN:

1. Are you currently taking medications? Yes No If yes, please list _____
2. Are you allergic to any medications? Yes No If yes, please list _____
3. Other allergies? Yes No If yes, please list _____
3. For female subjects:
   Do you think you might be pregnant? Yes No

FOR MRI TECHNOLOGIST USE ONLY

Database opt out Yes No Previous radiologist read date____/____/____ (MONTH) (DAY) (YEAR)

G. SIGNATURES:

In signing below, I certify that the information provided is complete and accurate to the best of my knowledge.

Signature of Participant completing form: _____ (SIGNATURE) Date____/____/____ (MONTH) (DAY) (YEAR)

_____ (PRINT NAME) _____ (RELATIONSHIP TO PARTICIPANT)

Form Information reviewed by: _____ (SIGNATURE) _____ (PRINT NAME)

☐ MRI Technologist ☐ PI ☐ GRA

Preliminary (phone) screen ____/____/____ (MONTH) (DAY) (YEAR) Second screen ____/____/____ (MONTH) (DAY) (YEAR) Final (day of) screen ____/____/____ (MONTH) (DAY) (YEAR)

Level 4 signature_____

Review Box

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Appendix C
Radiologist Dictation Form

KRASNOW MRI PARTICIPANT DICTATION

DATE OF STUDY

PARTICIPANT #

PARTICIPANT DOB **M or F**

☐ No significant findings noted.

☐ Incidental Finding. Inform PI to advise subject to follow up with family physician.

☐ Abnormal Finding. Inform PI to advise subject to follow up with family physician.

☐ Mild sinus inflammation, not of sufficient severity to require reporting to subject (extensive sinus abnormalities which do require reporting are noted below)

☐ Participant gave history of_____ and imaging concordant with that.

Recommendations:

_____ _____
Name, MD Date of Review

GMU Principal Investigator Action Items

☐ Principal Investigator forwarded documentation to MRI Technologist that participant was notified (documentation will be attached to this file sheet and retained by the MRI facility).

Date:_____

PI:_____ Print name:_____

Appendix D
Phantom Practicum

GEORGE MASON UNIVERSITY

KRASNOW MRI RESEARCH CERTIFYING CHECK LIST PHANTOM

Researcher being observed/evaluated:_____

Technologist observing:_____

Phantom Identifier:_____

Date:____/____/_____ **Time** _____ **to** _____

	OBSERVED	ASSISTED	INDEPENDENT	COMMENT
SCANNER ROOM PREPARATION				
Turning on scanner properly				
Operator(s) de-metaled				
Login to system				
Move table up & down, in bore				
Connect the head coil properly				
Phantom placement				
Power Supply on Scanner table				
Clean up room when finished , phantom placed in holder				
Proper positioning of inanimate object				
IN THE CONSOLE ROOM				
Knows who can and cannot be in the scanning room/console area at all times (not just during scanning session)				
Registration page				
Set up slice prescription				
Retrieve protocols				
Started all the sequences properly				
Turn scanner off properly				
Identify Axial, Sagittal, Coronal imaging planes				
SAFETY				
EPO red button(yellow rim),identify location & know when to use				
QUENCH red button (under plastic cover)				
Know the operator training requirements				
Fire extinguishers, identify location and know when to use				
Keep Scanner & Console room doors closed at all times				
Lock scanner room door when not in use				

3/14/2013

	OBSERVED	ASSISTED	INDEPENDENT	COMMENT
TROUBLESHOOTING				
Know where the error messages come up on scanner				
Know how to check /reboot MR scanner				
Know emergency numbers				
Know how to restart a sequence after failed or				
stopped sequences				
PAPERWORK				
Qualifying Event (employee incident)form				
Error log documentation				
IDENTIFICATION & LOCATION OF ITEMS				
MR Safe & UNSafe items				
Room supplies				
SOP's 1-9				
Exit checklist posted on door				
Flashlight				
Quench Sign				

Technologist:_____ **Date:**_____

3/14/2013

Appendix E
Human Practicum

GEORGE MASON UNIVERSITY

KRASNOW MRI RESEARCH CERTIFYING CHECK LIST – HUMAN (Revised 5-23-13)

Researcher being observed/evaluated:_____

Technologist/PI observing:_____

Participant de-identification:_____

Date:___/___/_____ **Time** _____ - _____

	N/A	OBSERVED	ASSISTED	INDEPENDENT	COMMENT
PARTICIPANT PREPARATION					
Study IRB consent signed					
MRI screening form completed and signed					
Weigh subject if necessary					
Participant de-metaled/changed clothing/used restroom					
Participant screened with hand held wand					
Eyeglasses removed/Hearing aid removed/colored contacts					
Subject re-scan within 1 year					
PARTICIPANT POSITIONING /SCAN PREP					
Sanitize hands before and after each participant					
Prep table & head cushion with paper					
Give participant earplugs/headphones					
Connect the head coil					
Position padding for head restraint/level of head					
Knee sponge/blanket / sheet provided					
Adjust mirror					
Provided padding at shoulder level					
Squeeze ball instructions given to participant & tested with participant					
Send participant into bore of scanner properly					
Communicate with participant before leaving scan room					
Move table up & down					
IN THE CONSOLE ROOM					
Register participant using unique identifier					
Communicate with participant before starting sequence					
Note on MRI screening sheet unique participant identifier					
Spoke to participant consistently between scans					
Worked in a timely manner					
Knows who can and cannot be in the scanning room/console area at all times (not just during scanning session)					

	N/A	OBSERVED	ASSISTED	INDEPENDENT	COMMENT
SCANNING					
Turn on scanner properly					
Login to system					
Scan phantom					
Retrieve protocols					
Set up slice prescription					
Spoke to participants consistently between sequences					
Demonstrate how to reposition head within circle scout					
Started all the sequences properly					
Worked in a timely manner					
Clean up room when finished , phantom placed in holder					
Turn scanner off properly					
SAFETY					
EPO red button(yellow rim), identify location & know when to use					
QUENCH red button (under plastic cover)					
What to do if the participant suddenly squeezes the blue ball					
Know the operator training requirements					
Fire extinguishers, identify location & know when to use					
Keep Scanner & Console room doors closed at all times					
TROUBLESHOOTING					
Know where the error messages come up on scanner					
Know how to check /reboot MR scanner					
Know emergency numbers					
FORMS PLACEMENT					
Know where to leave the MR Screening/Visitors sheet for Marci					
Adverse Event (participant incident)					
Qualifying Event (employee incident)					
fMRI/PARADIGM EQUIPMENT SET- UP (<u>if required</u>)					
Projector turned on/off correctly in MR computer room					
Dell computer or laptop set-up					
Current Designs or Lumina button box turned on/connected					
Movie/TV show queued up; volume adjusted					
Button boxes connected					
Experiment explained to participant					
Know how to set up paradigm on computer					
Tested button box with participant					
Be familiar with timing of trigger regarding the sequence					

Technologist /PI :_____ **Date:**_____

Appendix F
Training Levels 1-4 Objectives

LEVELS 1-4 TRAINING OBJECTIVES

Level 1

Function: To serve as a buddy to a Level 2 Operator to perform MRI Scanning on phantoms and inanimate objects. To achieve this level the candidate should be able to:

- Understand the magnet, its risks, and the limitations of the 5 Gauss line.
- Understand the purpose of safety screening conducted by the MRI Safety Manager and why it is necessary to be approved for safe entry into the MRI Suite.
- Demonstrate safe rescue of participant out of scanner room using MRI compatible stretcher.
- Learn how to safely enter the scanner room by removing all metallic objects (e.g., jewelry, clothing, etc.) for both researchers and participants.

Level 1 +

Function: To serve as a second operator to a Level 3, 4, 5 Operator to perform MRI Scanning on human participants. To achieve this level the following requirements for this candidate are:

- Successfully complete all requirements of Level 1 training.
- Obtain current CPR certification if scanning human participants in a research study.

Level 2

Function: To serve as an Operator to perform MRI scanning on phantoms and inanimate objects. To achieve this level the candidate must meet the following requirements:

- Demonstrate the following within the scanner room:
  - Table movement.
  - Coil placement.
  - Phantom placement.
  - Table connections.
  - Location of supplies.
- Identify the following within the scanner room:
  - Location of supplies.
  - MRI safe labeled items.
  - EPO and Quench buttons (and know their purpose).
  - Power supply on the scanner table.
- Demonstrate the following regarding the console room:
  - Know who can/cannot be in the console room while scanning.

        - Use de-identifiers on scanner registration page.
        - Set up slice prescriptions and start all sequences properly using phantom.
        - Turn on/off scanner properly.
        - Lock all doors to the scanner suite when not in use.
        - How to reboot MR scanner.
        - How to record errors and QA in the log book.
- Identify the following regarding the console room:
        - MR safe and unsafe items.
        - Emergency numbers.
        - Incident forms (employee, visitor, participant).

Level 3

Function: To serve as an Operator to perform MRI Scanning on human participants. To achieve this level, the candidate must meet the following requirements:

- Demonstrate the following with the participant who is volunteering for an MRI study before entering the MRI room:
        - Second MRI screening form signed (after MRI technologist completes by phone).
        - Participant de-metaled and verified using the hand held wand.
        - Participant weighed, if necessary.
        - Verify if participant has been scanned within the previous year.
        - Sanitize hands before and after each participant.
        - Participant's personal items locked and secured in screening for privacy.
        - Participant changed into compatible clothing, if necessary (e.g., sweatshirt).
        - IRB study consent signed.
        - External hearing and visual aids removed after explanation of exam has been given (e.g., glasses, colored contacts, hearing aids).
- Demonstrate the following with the participant who is volunteering for an MRI study after entering the MRI room:
        - Proper placement of earplugs and headphones for participant.
        - Provide proper positioning aids (sponge pads, knee sponge, blanket, etc.).
        - How to use the squeeze ball in an emergency.
        - Properly position participant's head in head coil and place participant in bore of magnet.

- Demonstrate the following tasks in the console room of the scanner suite while scanning a participant who is volunteering for an MRI study:
        - Register participant using unique identifier on scanner registration page.
        - Learn how to communicate with the participant using the intercom system.
        - Know the levels of scanning and verify who is able to be in the console room and who is not.
        - Turn on/off the scanner properly.
        - Login into system.
        - Retrieve protocols and set up slice prescriptions.
        - Set up and clean up room at start and end of scanning sessions.
        - Scan QA protocol after scanner has warmed up.

- Be able to set up fMRI using equipment provided.

Level 4

Function: To serve as an Independent Operator to perform MRI Scanning on human participants. To achieve this level, the candidate must meet the following requirements:

- To Achieve Level 4 status the PI /Post Doc candidate should be able to demonstrate /identify the following:
  - Demonstrate how to reset the circuit breaker box after pressing the EPO button.
  - Identify two ways to stop a sequence that is currently running.
  - Demonstrate a manual table release in the scanner room.
  - Demonstrate the steps of rescuing a participant out of the scanner room.
-
- To Achieve Level 4 status the PI/Post Doc candidate should be able to describe the following:
  - Describe the signs of claustrophobia that a participant may experience in the scanner room and how you would handle the participant.
  - Know the reasons when to use and when not to use both the Quench and EPO buttons.
  - What are the implications that could occur of improper demetaling before entering the scanner room?
  - Know where to locate the emergency SOP.
  - Knowing when you can scan with the scanner room door open.

Appendix G
Krasnow MRI Radiologist Consultation

KRASNOW MRI RADIOLOGIST CONSULTATION

DATE OF CONSULT:

PARTICIPANT NAME:

PARTICIPANT DOB: **M or F**

IMPLANT/SURGERY IN QUESTION:

☐ Yes, proceed to scan based on information provided on medical history sheet and/or previous surgical, diagnostic reports provided .

☐ No, do not proceed to scan. Unable to clarify implant without further diagnostic tests being ordered (e.g orbital X-ray, CT scan of body part in question)

☐ No, do not proceed to scan based on medical history and/or findings of previous surgical/diagnostic reports provided at time of consult.

Comments:

_____ _____
Name, MD Date of Review

GMU MRI Safety Manager Action Items

☐ PI notified by MRI Safety Manager

Date:_____ PI: _____ Study Name_____

Documentation will be attached to Participant's MRI screening sheet and retained by the MRI facility

☐ Invoice sent to Jane for billing. Date:_____

PI: _____

Study name:_____ Org # _____