THE UNIVERSITY OF TEXAS AT DALLAS
BRAINHEALTH®
IMAGING CENTER

UT DALLAS BRAINHEALTH IMAGING CENTER

(A 3T MRI CORE FACILITY)

MRI SAFETY POLICIES AND PROCEDURES MANUAL

As approved by
UT Dallas BrainHealth Imaging Center
Operations, Safety and Feasibility Ad Hoc Committee

March, 2021

Resources and Contact Information

	972-883-
UTD BrainHealth Imaging Center Director, Dr. Bart Rypma	3235
Administrative Coordinator, Angela Plata	3355
MRI Technologist, Jason Grubb	3472
Research Scientist, Sergey Cheshkov	3321
MRI Control Room	3422
Center for BrainHealth Chief Director, Dr. Sandi Chapman	3007
Vice President for Research, Dr. Joseph Pancrazio	2138
Assistant VP for Research Integrity and Outreach, Sanaz Okhovat	4579
Director, Institutional Review Board / Research Integrity and Outreach, Amanda Boone	4575

Table of Contents

SUPPLEMENT:
Re-Opening Guidelines and Procedures

In March, 2020, due to the Coronavirus/COVID-19 pandemic, UTD Office of Research shut down in-person human subject research. The BrainHealth Imaging Center suspended operations effective March 16, 2020. The "Re-Opening Guidelines and Procedures" were developed by the Imaging Center Director & staff, and vetted by the MRI Executive Advisory Board and Operations, Safety & Feasibility Ad Hoc Committee, to provide the safest methods of scanning for research staff and participants for use when human subject research is reinstated at UTD and BHIC can resume scanning services.

List of Figures

Acronyms

ACR	American College of Radiology
AED	Automated Emergency Defibrillator
ARRT	American Registry of Radiologic Technologists
BHIC	BrainHealth Imaging Center
BLS	Basic Life Support
CPR	Cardiopulmonary Resuscitation
dBA	Decibel (level A)
FDA	Food and Drug Administration
fMRI	Functional MRI
G	Gauss
IRB	Institutional Review Board
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
OSHA	Occupational Health & Safety Administration
PPE	Personal Protective Equipment
PI	Principal Investigator
RF	Radio Frequency
SAR	Specific Absorption Rate
T	Tesla
UTD	The University of Texas at Dallas
W/kg	Watt/kilogram

Foreword

The purpose of the *Magnetic Resonance Imaging (MRI) Safety Policies and Procedures Manual* is to provide a resource for safe MRI practices at the UT Dallas BrainHealth Imaging Center (BHIC). 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 publication, *ACR Guidance Document on MR Safe Practices: 2013*, was used as a primary reference for development of the MRI Safety Program at the University of Texas at Dallas (UTD).

This manual will be maintained at BHIC and made available upon request. The contents of this manual are reviewed periodically and revised as necessary to reflect changes in MRI safety and operations.

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

NOTE:
Policies & procedures within this manual are continuously reviewed and as the need arises, can/will be updated. It is research staff responsibility to find & review the most updated manual on the Imaging Center page of the Center for BrainHealth website

Document History

Version	Revision Date	Comments
1	January, 2020	Initial *MRI Safety Policies and Procedures Manual*
2	July, 2020	Updated as final following review by the MRI Operations, Safety & Feasibility Committee "Re-Opening Guidelines & Procedures" supplement added as required following Center shut-down due to COVID-19
3	Sept, 2020	UTD Institutional Review Board office released CayuseIRB for on-line IRB application submissions. UPDATE: BHIC MRI Operations, Safety & Feasibility Committee review & notification process.
4	Feb, 2021	Updated Emergency Procedures

1.0 Introduction

The UT Dallas BrainHealth Imaging Center (BHIC) is dedicated to providing resources for the acquisition and storage of brain image data to the UTD neuroscience community and encourages collaborations between institutions and scientists, disseminates products of our research, and shares the resources of the imaging suite.

The BHIC contains two (2) high-field 3 Tesla (T) Siemens Prisma MRI scanners. These magnets are full body scanners designed to accommodate high resolution structural scans of all body parts, and structural and functional imaging of the human brain. They have 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, the BHIC 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 Hazards Associated with MRI

1.1.1 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 (G) line should be clearly demarcated and the area within that line kept free of ferromagnetic objects. Personnel and research participants must remove all metallic personal belongings (hearing aids, analog 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 (fire extinguisher, etc.) must be made of nonferrous material and be classified as MR safe.

1.1.2 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, devices, and other objects that are not proven MR safe pose a serious health risk due to torque, heating, and other risks. Items tested to be safe at 1.5T are not necessarily safe at 3T. All items must be documented as MR safe or MR conditional before being

permitted in the MRI Suite. MR conditional items must be verified to meet the specific conditions of the BHIC MR (Magnetic Resonance) environment.

To prevent damage or injury due to heating, stimulation, 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 or other conditions that would contraindicate presence in a high field strength environment. 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.

1.1.3 Cryogenic Liquids and Quench

The coils of the superconducting magnet are immersed in liquid helium to prevent excessive heat buildup. Under normal operation, the helium may slowly boil off and more liquid helium must be added. Risks associated with liquid helium include frostbite 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 by a ferromagnetic object. In extraordinary circumstances, an uncontrolled quench can occur. In either 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 room that houses the magnet has a specialized ventilation system. In the event of a quench, it is possible for the scanner suite to become pressurized and prevent the door from opening inward. Due to this risk, the rooms are equipped with removable wall panels that release outward to equalize the pressure, allowing the door to be opened.

1.1.4 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). These effects may be minimized by avoiding rapid movements within the bore of the scanner.

1.1.5 Radiofrequency Fields

The MRI signal is created by radiofrequency fields (RF) pulsing 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 Food and Drug Administration (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.

1.1.6 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 (dBA). The Occupational Health and Safety Administration (OSHA) permissible exposure limit for noise is 90 dBA over an 8-hour workday, with a 50% reduction in permissible exposure duration for every 5 dBA above the 90 dBA limit. Ear plugs or ear muffs can both reduce noise exposures by 20-30 dBA; used in combination, the noise exposure is reduced by an additional 5 dBA.

All employees working in Zone IV are required to wear disposable ear plugs and/or headphones while the scanner is in operation.

Non-employee study participants and/or escorts involved in MRI studies are required to wear disposable foam ear plugs and/or headphones while the scanner is in operation.

1.2 Facility Design

1.2.1 Safety Zones

The BHIC is divided into four zones **(Figure 1)**. This classification, as suggested by the American College of Radiology (ACR), is commonly used in facility planning and discussions about MR safety. The design of the four MR zones in the BHIC considers the ACR recommendations.

Zone I includes all areas outside of the BHIC that are freely accessible to the general public. These areas include the Brain Performance Institute's (BPI) main lobby, public restrooms, elevators, etc. There are no restrictions, screening or training required for anyone in these areas.

Zone II is the interface between the uncontrolled Zone I and the strictly-controlled Zone III. It is comprised of the hallways and rooms within the BHIC including the reception and waiting areas, restrooms, training/interview rooms, lockers, changing room, offices and janitorial closet. This is the area where gowning and screening for Zone III access occurs. Public individuals in this area are supervised by personnel who have completed MR safety training.

Zone III is the MR Control Room and equipment rooms where access by unscreened individuals is prohibited and the introduction of ferromagnetic objects or equipment is highly restricted. Free access is limited to Level 1 and 2 MR personnel only (see **Section 1.6: Visitor and Staff Classifications**). Public and non-MR personnel entry is controlled by Level 2 MR personnel only and individuals in this area must be screened and under the supervision of Level 2 MR personnel at all times.

Zone IV consists of each of the two (2) rooms where the MR scanners are located. Access to these areas is highly restricted due to the dangers that exist in the MR environment that could result in equipment damage, personal injury and death. These rooms are accessible to Level 2 personnel only. Entry is controlled by Level 2 MR personnel only and all other

individuals in this area must be screened and under the supervision of Level 2 MR personnel at all times.

Entrances to Zones II, III and IV (hereinafter referred to as the "MRI Suite") are posted with signage to indicate the zone level and details of the hazards and restrictions.

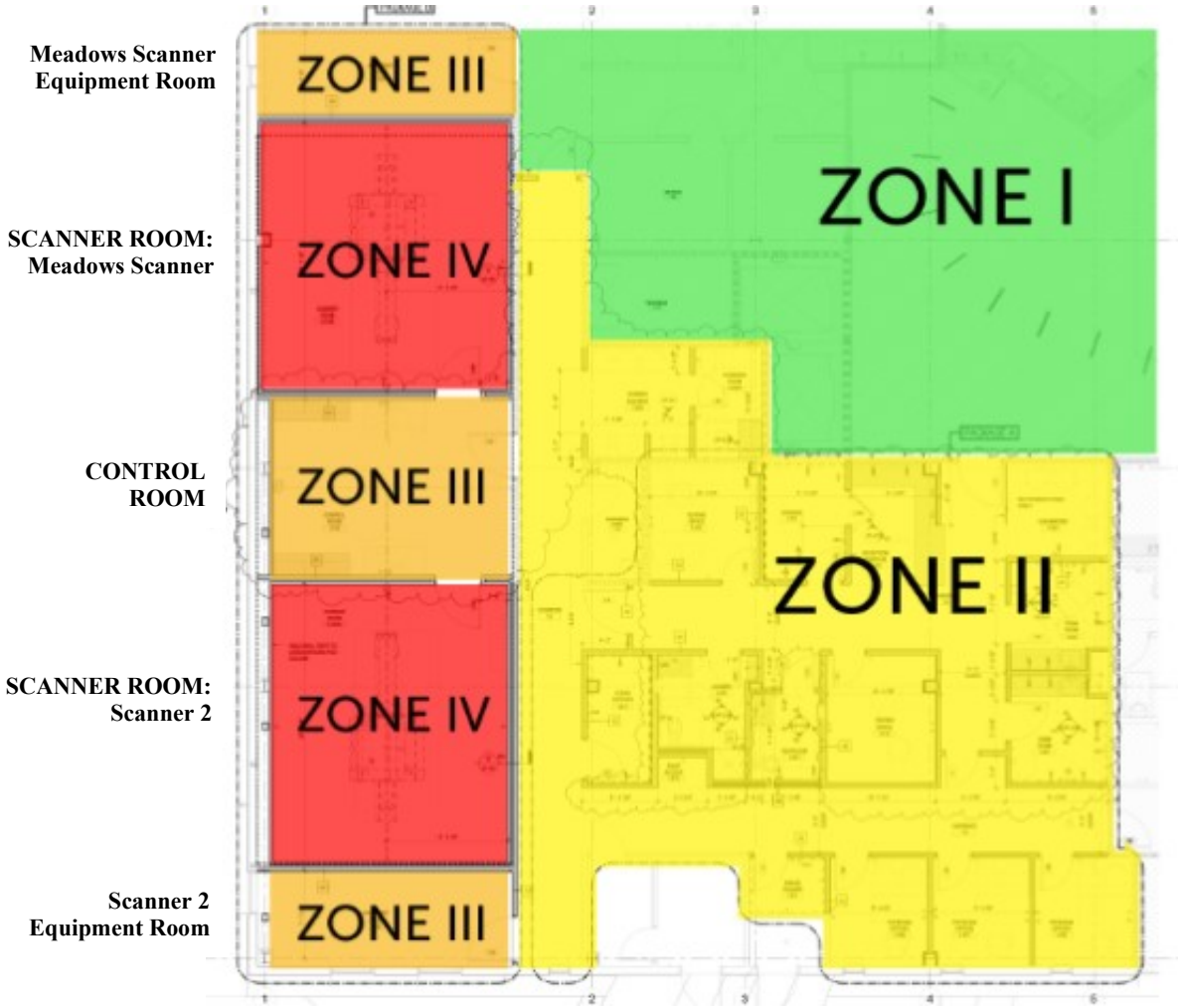


Figure 1: BHIC MR Zones

1.2.2 Shielding

Each Scanner Room (Zone IV) is shielded by copper on all six sides. The wave guides, which permit functional imaging equipment and other systems to attach to the MRI, are also constructed of copper. The copper shielding protects the magnetic environment from outside RF contamination. The shielding contains the magnetic field so that the hallway (Zone II) is free of the magnetic field. The location of the 5 gauss (0.5 mT) line is demarcated on the floor in Zone IV to indicate the pacemaker exclusionary zone. Conductive wires must not be allowed to pass through the wave guides at any time. Fiber optic wiring and tubing used to pass liquid or gas is permissible through the wave guides.

1.2.3 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. A quench is accompanied by a loud noise, which may startle persons in the facility and in the surrounding area, but the helium released to the outside is lighter than air, is inert, and is not harmful to the environment.

1.2.4 Labeling Requirements

Equipment, instruments, and devices must be clearly labeled to indicate their safety for use in the MR environment. Three types of labels **(Figure 2)** 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).

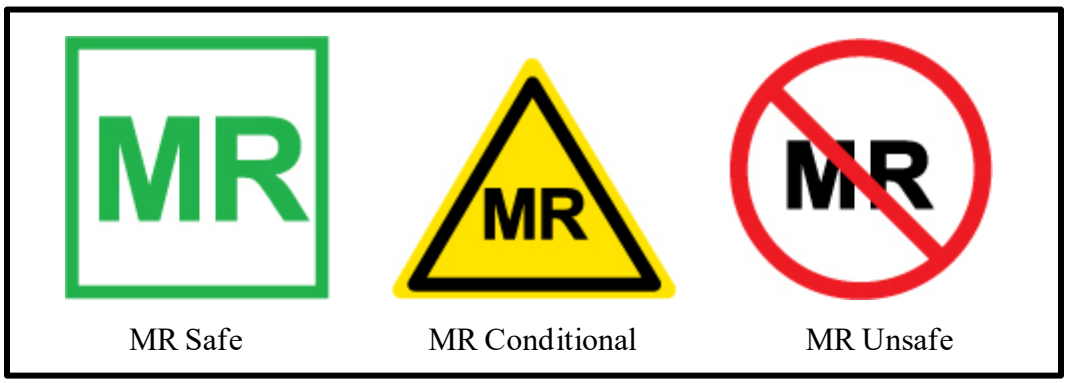


Figure 2: ASTM Labeling

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. An object with this label warns the user that there are limitations to the usability or to the testing that was performed on it. For example, the object may have been tested for a 1.5T system, but not for a 3T system. The conditions should be included on the object, its packaging, or its accompanying instructions. All conditions must be compared to the specifications of the scanner to establish whether the requirements can be met. If any conditions cannot be met, the object must not be subjected to those conditions.

MR Unsafe is defined as an object that poses a known threat or hazard in all MR environments. These objects may never be allowed in Zone IV.

1.2.5 Equipment and Supplies

The MRI Suite is equipped with MR compatible supplies for housekeeping, MR conditional fire extinguishers, stretcher, and wheelchair in case of a medical emergency.

All equipment for use in the MRI Suite is labeled regarding suitability for the MR environment.

The closest portable Automated External Defibrillator (AED) is located in the hallway outside of the MRI Control Room. The AED is MR unsafe and should not be brought past Zone II. If necessary, it can be brought into the Control Room but must remain outside Zone IV/Scanner Room(s).

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, research participants, UTD 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 UT Dallas

2.1.1 Vice President for Research

The UTD President delegates authority to the Vice President for Research, who is charged with overseeing all aspects of UTD's research programs. Specific responsibilities of the Vice President for Research with regard to MRI safety are to:

- Provide operational funding, guidance and administrative support as required to maintain MRI research operations to meet all established safety, legal, and ethical regulations or guidelines applicable to MRI research operations; and
- Serve as a member of the BHIC MRI Executive Advisory Board.

2.1.2 UTD Institutional Review Board (IRB)

The UTD IRB reviews all research studies involving human participants prior to initiation of the project. Information pertaining to the Office of Research guidelines surrounding Human Subject Research can be found on their website.

Investigators 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 the required Human Subjects Protection training accessible via UTD's eLearning.

For IRB approval, all participant consent forms must clearly state the purposes of the MRI scanning that will be conducted, and that (1) the researchers are not medical personnel; (2) that the MRI scans are intended for research purposes only; (3) that the images produced by the MRI are not of sufficient quality for medical diagnosis; (4) the participant should not expect any clinical evaluation or review of MRI scans by medical personnel; and (5) if the researcher notices anything abnormal in a participant's scans, he or she will follow procedures as outlined in **Section 11: Incidental Findings**.

2.2 UTD BrainHealth Imaging Center

2.2.1 MRI Executive Advisory Board

The MRI Executive Advisory Board (Executive Board) members shall meet periodically to review the state and welfare of the BHIC. They will provide operational, administrative and policy guidance for center-wide operations to the BHIC Operations, Safety and Feasibility Ad Hoc Committee and help address issues that arise. They will provide ongoing recommendations, at least annually, on the business plan and make recommendations or appraisals on operations and services, at least bi-annually. They will work to build community relations to advance the interests of the BHIC and meet the needs of its users.

2.2.2 Operations, Safety and Feasibility Ad Hoc Committee

The BHIC Director, in consultation with the Vice President for Research, the Center for BrainHealth Director and Deputy Director(s), and Research Integrity and Outreach officers appoint members of the BHIC Operations, Safety & Feasibility Ad Hoc Committee (Safety Committee). The Safety Committee will be comprised of at least six (6) standing faculty members, members from the Office of Research, and the MRI Technologist(s).

Specific responsibilities of the BHIC Operations, Safety & Feasibility Ad Hoc Committee are to:

- Review and approve policies and procedures regarding safe operation of the BHIC as necessary.
- Review, approve and consult on investigator-initiated study protocol proposals to be implemented at the BHIC and as submitted using the on-line platform CayuseIRB.
- Conduct periodic review of the *MRI Safety Policies and Procedures Manual*.
- Participate, as requested by the BHIC Director, in incident investigations for unexpected or adverse events taking place at the BHIC.
- Review and consult on BHIC operations.

2.2.3 BrainHealth Imaging Center (BHIC) Director

The BHIC Director provides scientific oversight and technical support for research operation of the UTD BHIC. Specific responsibilities with regard to MRI safety are to coordinate with the Vice President for Research, Center for BrainHealth Chief Director and Deputy Director to ensure compliance with UTD policies and procedures, as well as the Office of Research Integrity and Outreach regarding IRB policies and protocols. These activities include:

- Along with IRB Director, appoint members to the BHIC Operations, Safety & Feasibility Ad Hoc Committee;
- Serve as member of the BHIC MRI Executive Advisory Board;
- Provide the necessary support for the conduct of research in the BHIC; and
- Coordinate with the MRI Technologist on emergency response procedures.

2.2.4 MRI Technologist

The MRI Technologist is an American Registry of Radiologic Technologists (ARRT) MR registered professional with the knowledge and experience to manage day-to-day operation of the BHIC. The MRI Technologist's primary function is to support the research activities conducted within the BHIC by Principal Investigators (PI), as well as overseeing the safe operation of the MRI scanner in compliance with all relevant regulations, policies and procedures.

The MRI Technologist has the authority to immediately cease or suspend unsafe activities, or activities that are out of compliance with UTD and/or BHIC policies and procedures and applicable regulations. Any such activities shall be reported and reviewed by the BHIC Director, the BHIC Operations, Safety & Feasibility Ad Hoc Committee, and the Office of Research. Specific responsibilities of the MRI Technologist include:

- Maintain safe operations within the BHIC while on shift.
- Maintain appropriate certifications to include ARRT certification and Basic Life Support (BLS) CPR training.
- Maintain current knowledge of functional MRI protocols utilized in the BHIC and be able to assist investigators in setting up new protocols.
- Monitor and implement policies and procedures for safety and operations of the BHIC.
- Conduct MRI safety and operational training for research personnel & other staff as required.
- Conduct routine instrument testing and calibration, in consultation with the equipment manufacturer.
- Report any identified incidental findings to the PI, and assist the PI with radiologist consultation as requested.
- Maintain documentation and records for safety and compliance, user & operator training, equipment service and maintenance, participant screening, and quality assurance data as required.
- 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 BHIC Director.
- Conduct safety screening of all users of the BHIC as a component of MRI safety training, and approve or deny access to the MRI Suite based on training proficiency and screening results.
- Maintain a participant log/database.
- Maintain inventory of Personal Protective Equipment (PPE), general office supplies as well as specific supply needs of the control room to ensure smooth operation of the MRI Suite.
- Enforce access restrictions to the BHIC.
- Respond to after-hours emergencies as needed.
- Perform or coordinate routine cleaning and maintenance of the BHIC (includes cleaning floors and surfaces, leaving trash cans outside of the facility in the main hallway to be emptied by housekeeping staff, etc.).

- Operate the MRI scanners 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 research participants for scanning, converse with participants during scanning, remove participants from the scanner after scanning, and conduct follow-up interviews with participants after scanning.
- Support users of the MRI scanners with paradigm implementation and other needed assistance.
- Organize, archive, and facilitate the transfer of acquired imaging data.
- Monitor and maintain temperature requirements for the scanner (water and helium levels).

2.2.5 Research Scientist

The Research Scientist will assist the Technologist in all phases of his or her work. He or she will help develop MRI protocols for all projects that have been approved by the BHIC Operations, Safety & Feasibility Ad Hoc Committee and the IRB. The Research Scientist will oversee advanced studies including inhalation and studies with peripheral devices. In addition, he or she will participate in meetings with collaborators for multi-site projects. Specific responsibilities include:

- Review quality control documents and periodically assess MRI data quality.
- Review data for consistency and manage impact of software upgrades.
- Assist users with issues on programming tasks, data transfer, format conversion, analysis, and other similar activities.
- Collaborate with users on data analysis.
- Train and certify users to perform gas inhalation studies. Assure that required supplies are available.
- Oversee and develop MRI pulse programming to implement novel MRI sequences.
- Install, test and troubleshoot functional MRI (fMRI) peripheral devices such as eye tracker, computers, and fMRI console for fMRI tasks.
- Work with the MRI Technologist to resolve technical issues, and if required, work with the MRI vendors, which may include scientists and engineers. Work with UTD Facilities Management for issues related to maintenance of humidity, temperature in the scanner and equipment room.
- Participate in publishing papers and writing grants using MRI data.
- Certify, in coordination with the MRI Technologist, users who will operate the MRI scanner independently (without the Technologist).

2.2.6 Imaging Center Administrative Coordinator

The Imaging Center Administrative Coordinator will work in consultation with the MRI Technologist and Director to oversee day-to-day functions of the BHIC. The Coordinator will provide oversight regarding the scanning schedule and manage billing. The Coordinator will assure friendly and efficient customer service and communication between all staff and Principal Investigators (PI). The Coordinator will, as needed, greet

research participants and personnel, assist in screening, prepare participants for scanning, and post-scan activities. The Coordinator will maintain documentation of actual scanning time to generate monthly billing. The Coordinator will be responsible, along with the MRI Technologist and Director, for the safety and welfare of personnel and study participant safety. The Coordinator will procure supplies needed in the BHIC.

2.3 Other Roles

2.3.1 Principal Investigator (PI)

PIs are responsible for overseeing the activities of all research staff assigned to execute their MRI experiments. It is the responsibility of the PI to follow BHIC policies and procedures and to ensure that all required 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 BHIC and for human subject research.
- Obtain the appropriate approval from the IRB for conducting research in the BHIC.
- Require that all MRI Operators involved in their research maintain training requirements, and follow all relevant BHIC policies and procedures and IRB requirements.
- Communicate instances of accidents and unsafe work conditions to the MRI Technologist, BHIC Director and the IRB.
- Notify research subjects of incidental findings and report findings to the IRB in accordance with IRB policies and procedures.
- Implement and ensure compliance with UTD policies regarding the transfer, use, and archiving of sensitive data.
- Inform personnel of potential hazards associated with MRI research and provide access to the *MRI Safety Policies and Procedures Manual*.
- Follow additional MRI Operator responsibilities as outlined below.

2.3.2 MRI Operators

MRI Operators are those users who have completed the required training & received approval from the MRI Technologist, in collaboration with the Research Scientist and/or Director, to work independently at the BHIC. It is the responsibility of all MRI Operators to conduct MRI research in a manner that will not adversely impact themselves, other personnel, research participants, the surrounding community, or the environment. Specific responsibilities of MRI Operators are to:

- Be familiar with the contents of this manual.
- Maintain appropriate training status and certifications.
- Limit operations within the BHIC to only those protocols or operations for which they have been approved.
- Report incidents, accidents, and near-miss events occurring within the BHIC to their PI, the BHIC Director and the MRI Technologist.

- Follow all UTD policies and procedures for MRI safety and human subject research.
- Be knowledgeable of:
  - BHIC-specific emergency procedures, contact information, and evacuation procedures.
  - BHIC-specific procedures for managing participants, operating the scanner, recordkeeping, data management, housekeeping, and maintenance reporting.
  - Location, use, storage, and maintenance of PPE and operational supplies.
  - Access restrictions and procedures for reporting unknown or suspicious individuals seeking access to the BHIC.

3.0 Security and Access

Unauthorized access to the BHIC 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 Scanner Rooms, Equipment Rooms and Control Room are **restricted access** rooms.

Access to the BHIC is controlled by electronic card access (Comet Card). Anyone requesting access to the BHIC must successfully complete MRI Safety Training and receive approval from the MRI Technologist administering the safety training program.

Access to the scanner rooms are controlled by manual key access. Unsupervised access is restricted to those individuals certified to operate the scanner; those who may need to enter the control, equipment, or scanner rooms in the event of an incident or emergency; and authorized individuals who may need to provide access to service personnel. No one is permitted supervised or unsupervised access without appropriate notification of the potential risks associated with the magnet. Keys and access cards to the BHIC must be kept in a secure location and may not be shared or loaned to other personnel.

Personnel who enter the MRI Suite must be involved in an approved MRI research study or be involved in authorized administrative or maintenance activities.

3.1 Tour Groups

Those who wish to tour the BHIC must notify the MRI Technologist and/or Imaging Center Administrative Coordinator prior to entering the MRI Suite. Visitors must be escorted at all times by the MRI Technologist or Research Scientist. Prior to entry into Zone III, visitors must be briefed regarding hazards associated with the MRI and, at the discretion of the MRI Technologist or Research Scientist, may be asked to complete an *MRI Safety Screening Form*. Visitors may not enter the MRI Scanner Room and 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 will only be conducted when the scanners are not in use.

3.2 Staff and Visitor Classifications

The description of visitor and staff classifications are provided below and a grid indicating the level of access to each MRI Zone is shown in **Figure 3**.

3.2.1 Public Individuals

Public Individuals are generally visitors to the BHIC, including research participants, their family members, vendors and other untrained individuals. They require no training and must be supervised in all areas of the BHIC by personnel who have completed Level 2 MRI safety training. The personnel level required for supervision varies by zone.

3.2.2 Research Participants

Research participants are individuals who after initial screening, have met all the inclusion criteria to participate in an approved research study. All research participants must be escorted in Zones III and IV by Level 2 MR Personnel.

3.2.3 Non-MR Personnel

Non-MR Personnel are generally UTD staff at the BrainHealth campus (Center for BrainHealth and Brain Performance Institute buildings). They are trained to safely access Zone II of the BHIC. They are unable to freely access or admit anyone into Zone III or IV. If they require entry into Zone III or IV, they must be screened and supervised by Level 2 MR personnel only.

3.2.4 Level 1 MR Personnel

Level 1 Personnel are trained to observe, assist or work in the MRI Control Room. This typically includes staff from IT, security, facilities, research faculty, and other staff and students involved in research studies. They are unable to freely access the scanner rooms, operate the scanners, or admit anyone into Zone III or IV. For Zone IV access, they must be screened and supervised by Level 2 MR personnel.

3.2.5 Level 2 MR Personnel

Level 2 Personnel includes MRI Technologists, all other trained MRI Operators and research faculty, staff and students involved in research studies who have completed the appropriate training. They can access the control room and scanner rooms and are able to screen and supervise individuals in all zones including III and IV.

3.2.6 Ancillary Personnel

Ancillary Personnel are housekeeping staff, facilities and maintenance personnel and are not permitted to enter Zones III or IV unless screened, escorted and supervised by Level 2 MR Personnel. The MRI Technologist will be responsible for cleaning Zones III and IV to avoid the need for housekeeping staff to enter these restricted areas. Trash is placed in the Zone II hallway for collection by the housekeeping staff.

3.2.7 Pregnant Staff, Researchers, and Participants

For safety reason, women who are pregnant will not be scanned as part of research protocols unless a specific protocol involving pregnant women is approved by the IRB.

Female researchers or technologists who are pregnant may not enter the scanner room to attend to participants, regardless of their trimester, as long as the scanner is in operation. Otherwise, pregnant women (i.e., staff, technologist, family member, or participant) will not be allowed to remain in the scanner room while the scanner is in operation and may not enter the scanner bore at any time.

3.2.8 Minors, Adult Volunteers and Research Assistants

Other than study participants, individuals under the age of 18 are not permitted in Zone IV.

Adult volunteers who have completed Level 1 MRI Safety Training may observe research activities in Zones II and III. Adult research assistants who are not affiliated with UTD are not permitted in the MRI Scanner Room(s).

	PUBLIC	NON-MR PERSONNEL	LEVEL 1 MR PERSONNEL	LEVEL 2 MR PERSONNEL
Zone I	FREE ACCESS	FREE ACCESS	FREE ACCESS	FREE ACCESS
Zone II	SUPERVISED	FREE ACCESS	FREE ACCESS	FREE ACCESS
Zone III	SCREENED AND SUPERVISED BY LEVEL 2	SCREENED AND SUPERVISED BY LEVEL 2	FREE ACCESS	FREE ACCESS
Zone IV	SCREENED AND SUPERVISED BY LEVEL 2	SCREENED AND SUPERVISED BY LEVEL 2	SCREENED AND SUPERVISED BY LEVEL 2	FREE ACCESS

Figure 3: MRI Zone Access

Exceptions: Siemens service engineers, trainers and certain reps may be granted access to the MRI Suite and can be admitted to Zone III by Level 2 MR Personnel or by Level 1 MR Personnel if necessary (e.g. after regular business hours).

4.0 Training

For a research study, there must be a minimum of two qualified individuals present in the control room at all times during an MRI scan procedure. At least one of the individuals must be an MRI Technologist or approved MRI Operator for the research scan being conducted. The second individual must be qualified and physically able to respond as necessary during an MRI emergency situation, must have completed Level 2 MRI Safety Training, and have current certification in cardiopulmonary resuscitation (CPR).

The description of personnel training requirements, along with a training matrix, is provided in **Figure 4**.

	Non-MR Personnel	Level 1 MR Personnel	Level 2 MR Personnel	Independent Operator
Basic/Non-MR Video + Test	X	X	X	X
Level 1 Video + Test		X		
Level 2 Video + Test			X	X
BHIC Orientation			X	X
CPR (basic life-saving) Certified			X	X
Operator Checklist & Researcher Acknowledgement				X

Figure 4: MR Personnel Training Matrix

4.1 Non-MR Personnel Safety Training

Non-MR training provides a basic overview of MRI safety, risks and restrictions. It is recommended for most personnel who work on the BrainHealth campus to ensure everyone is aware of the basic dangers of the magnets and has a general understanding of the access restrictions. Generally, no access is granted by this training; however, personnel who complete this training **may** be granted access to Zone II (ex: receptionist). The training is delivered online and consists of a video and short quiz and must be repeated annually. Non-MR Personnel training is a prerequisite for Level 1 and/or Level 2 MR Personnel safety training.

4.2 Level 1 MR Personnel Safety Training

Level 1 training is required for personnel who observe, assist or work in Zone III. The training sessions will be scheduled and delivered as needed to provide a deeper understanding of MR safety, risks, restrictions, procedures and responsibilities. Participants must watch a video and presentation, pass a short quiz on the covered material, complete an orientation visit of the BHIC, complete the *MRI Safety Screening Form*, and repeat the training annually. The MRI Technologist is responsible for delivering a portion of this training course.

4.3 Level 2 MR Personnel Safety Training

Level 2 training is required for all personnel who may operate the MR scanners, need access to Zone IV and/or screen, admit, escort and supervise individuals in Zone III or IV. The sessions will be scheduled and delivered as needed to provide an advanced understanding of MR safety, risks, restrictions, procedures and responsibilities. Topics include participant screening, medical device and implant safety and other safety issues related to the potential for thermal loading, burns and nerve stimulation from rapidly changing gradients. Personnel must pass a short quiz on the covered material, complete an orientation visit of the BHIC, complete the *MRI Safety Screening Form*, and repeat the training annually. The MRI Technologist is responsible for delivering portions of this training course. This program does not train or evaluate individuals to operate the scanners. Level 2 MR Safety Training is a prerequisite for MRI Operator Training.

4.4 MRI Operator Training*

Level 2 MR personnel who are interested in becoming an MRI Operator for specific research protocols in order to utilize the BHIC without the MRI Technologist present, must first receive training on the Siemens Prisma 3T MRI scanner(s). MRI Operator Training will be conducted by the MRI Technologist, certified by the Research Scientist and will include hands-on training of scanner operation procedures, review of specific procedures for incident and emergency response, identification and evaluation of incidental findings, and techniques for managing participants before, during, and after scanning.

Upon completion of hands-on MRI Operator Training, a trainee may be eligible for supervised scan time under the direct supervision of the MRI Technologist or Research Scientist. During this time, the trainee receives any necessary additional hands-on training from the MRI Technologist until both the trainer and trainee feel they are able to confidently operate the scanner for the specific protocol or protocols for which they are seeking MRI Operator approval.

Trainees are encouraged to continue to scan with supervision until they are proficient and the trainer is confident in their abilities to operate the scanner independently.

MRI Operator Competency Checklist

Trainees who have completed the appropriate amount of supervised scan time will be evaluated by the MRI Technologist or Research Scientist to test the trainee's competency, ability to operate the scanner independently, and ability to respond appropriately to emergencies using the *MRI Operator Competency Checklist* **(See Appendix A)**.

Depending on outcome of the initial evaluation, a trainee may be required to complete additional supervised scan time before being re-evaluated. 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.

*Operator Training is currently suspended. Inquiries regarding reinstatement of the program should be directed to the Imaging Center Administrative Coordinator or MRI Technologist.

4.5 CPR Training and Certification

The MRI Technologist, MRI Operators, Level 2 MR Personnel who will serve as secondary operator for scans of research participants, and personnel who are trained at MRI Level 2 with unescorted access to Zones III or IV, must have current CPR (Basic Life Support) certification. Training is periodically offered at UTD main campus or the researcher/operator may obtain training from an outside provider. A copy of an unexpired CPR certificate must be provided to the Imaging Center Administrative Coordinator.

5.0 MRI Safety Screening

All individuals, including operators, researchers, staff, students, research participants, and visitors must be screened prior to entering the MRI Control Room (Zone III). The BHIC *MRI Safety Screening Form* **(See Appendix B)** is used to evaluate the safety of each person before that person is permitted in Zones III and/or IV. It is a comprehensive safety screening tool based on standardized forms & criteria promoted by MRI experts. The completed forms must be reviewed, approved and signed by Level 2 MR Personnel prior to entry to the MRI Suite.

MRI safety screening of anyone who is cognitively impaired must adhere to the definition of "cognitively impaired" as defined by the IRB.

When screening minors or anyone who is cognitively impaired, or who is compromised with respect to making decisions about their medical history, the MRI Technologist or any other trained MRI Operator must be able to verify that the individual who is signing the MRI Safety Screening Form is appropriately authorized to do so on the participant's behalf.

5.1 Screening Researchers, Staff, and Students

Operators, researchers, staff, and students who intend to enter the MRI Suite should be screened by the MRI Technologist prior to attending MRI Level 1 or 2 Safety Training. Screening for these individuals must be updated on an annual basis. Additionally, it is the responsibility of these individuals to notify the screener if a contraindication (such as pregnancy, surgery, or injuries involving ferromagnetic material) should arise that could prevent them from entering Zone IV/scanner room.

5.2 Screening Research Participants

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

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

If a research participant has any conditions listed below in **Section 5.5** - *Mandatory Exclusionary Criteria*, they are automatically excluded from participating in an MRI study at the BHIC. The PI may also decide to exclude participants that have items listed in **Section 5.6 -** *Criteria that May Exclude Research Participants,* or if the participant experiences claustrophobia or any other condition that contraindicates study participation.

If the research participant has had any type of surgery, or has any of the implants or devices listed in **Section 5.6**, the MRI Technologist has the authority to approve or exclude the research participant. All implants and devices, whether MR safe or not, must be

documented on the MRI Safety Screening Form, and the following information must be collected for each device or implant:

- Type
- Manufacturer
- Make or model
- Serial number

For surgical implants, an implant identification card may be provided. This information may also be collected if the research participant is willing to provide a surgical report. Information must be sufficient to verify the compatibility of the implant with the BHIC MR environment. The PI is responsible for forwarding the necessary information to the MRI Technologist for review.

The second screening is conducted by the MRI Technologist or qualified MRI Operator immediately prior to escorting the participant into the MRI scanner room for their scheduled scan. The MRI Technologist or qualified MRI Operator may cancel or postpone a scan if the research participant's second screening raises concerns about the suitability of the participant for the MRI environment. A file of the second screening of each participant will be maintained by the PI.

5.3 Screening Companions

Visitors who accompany research participants into the scanner room must pass the safety screening conducted using the *MRI Safety Screening Form*.

5.4 Screening Minors as a Participant

Anyone under the age of 18 who requires a scan must have a parent or legal guardian present at time of screening in order to provide the required signature on the *MRI Safety Screening Form*.

5.5 Mandatory Exclusionary Criteria

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

- 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)
- Certain electronic implants or devices
- 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)
- Neurostimulator system, spinal cord stimulator, bone growth/bone fusion stimulator
- Aneurysm clips or coils

- Endoscopy capsule camera
- Any type of non-removable pump (pain, drug infusion, insulin, etc.)
- Tattoos above the neck to include permanent cosmetics (e.g., eye or lip liner, etc.)
- Certain ear surgeries, implants (cochlear and otologic), stapes, prosthetic ear bone
- For males, penile implant
- Any item labeled MR unsafe
- Any item labeled MR conditional that is not deemed compatible for use in the BHIC 3T scanners
- Any item for which clear and unambiguous documentation cannot be provided to verify the item is compatible with the BHIC 3T scanners

5.6 Criteria that May Exclude Research Participants

As some of these items may affect image quality, clearance by the MRI Technologist is required for research participants with any of the following conditions:

- History of surgical procedures that may or may not contain implants
- Injury involving a metallic object or metallic 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
- For females, Intrauterine Device (IUD)
- Shunts (spinal or intraventricular)
- Vascular access port and or catheter
- Wire mesh implant
- Heart valve prosthesis
- Insulin pump
- Metallic stents, filters, or coils
- Medication patches (nicotine, nitroglycerine, contraceptive, pain)
- Other implants and items not listed above

5.7 Clearance Procedure for Devices and Implants

Research participants with implants or devices will not be permitted to participate in an MRI study unless clear and unambiguous documentation verifies that the item is compatible with the BHIC 3T scanners. The PI is responsible for forwarding the preliminary screening form and required documentation to the MRI Technologist. The MRI Technologist, in consultation with study PI or other responsible individual as appropriate, will recommend whether to approve or exclude a research participant. If, after consultation, it is determined that the device or implant is MR compatible, the PI may continue to include the participant in the study. For a device to be recommended as compatible for a scan, the following criteria must be met:

- Clear and unambiguous documentation exists verifying that the device or implant is compatible with the 3T scanners at the BHIC, or
- The implant is shown to be compatible according to the *Reference Manual for Magnetic Resonance Safety, Implants and Devices*, by Frank G. Shellock, PhD, or www.mrisafety.com.

5.8 Removable Items

The following items must be removed before entering into the Control or Scanner Room. Any or all of the following items may result in injury and/or damage to the item, the scanner, other equipment, or people in the vicinity.

- Insulin pumps (an exception may 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 scan 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. 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 the inside of the bore of the magnet. If needed, the facility does have MR safe frames and lenses available.
- Dentures, partial plates, and nonpermanent retainers. All dental work that is removable should be removed. These items are to be removed even if no metal is visibly seen to ensure no artifact would be present on the images.
- Clothing made with metallic components. Participants may arrive with clothing made with metallic threads and/or metallic decorative artwork. This type of fabric may tend 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. MRI safe clothing will be provided for the participant to wear for the duration of the scan.

6.0 Project Review and Approval

All research involving MRI scans of research participants must be approved by the BHIC Operations, Safety & Feasibility Ad Hoc Committee and the Institutional Review Board (IRB) prior to commencement of work. All research proposed by non-UTD investigators must be approved by their own organization's IRB, in addition to the above-mentioned groups, and a copy of that approval and protocol must be provided to the BHIC Director and the UTD IRB prior to commencement of work.

6.1 Operations, Safety & Feasibility Ad Hoc Committee Review and Approval

The BHIC Operations, Safety & Feasibility Ad Hoc Committee (Safety Committee) reviews proposals to utilize the BHIC facilities involving research participants prior to initiation of the project. Applications must be submitted to the IRB via the on-line platform, CayuseIRB. The application will be assigned to the "MRI Safety & Feasibility" and the Imaging Center Administrative Coordinator, acting in the Analyst role, will work with the Safety Committee Chair to assign reviewers within the system.

PIs must make sure that proposals submitted to the BHIC conform to the regulations and procedures listed in this manual. Each new application will, with oversight from Safety Committee Chair, be assigned two (2) committee reviewers who will present observations including but not limited to:

- How the study is funded
- Roles of the personnel
- Equipment to be utilized
- Populations to be tested/scanned
- Proposed study design as it relates to safety for research participants & personnel and assuring high standard of scientific integrity

The Committee Chair will communicate decision results and/or approval to the PI. Decision letter(s) will be uploaded into CayuseIRB and upon final approval by the Safety Committee, the application will be returned to IRB analysts for further review. The PI must ensure that, upon study approval, all personnel who will be conducting MRI research have successfully completed MRI safety training.

6.2 IRB Review and Approval

Following approval of the BHIC Operations, Safety & Feasibility Ad Hoc Committee, the application is returned to IRB analysts via the CayuseIRB system. The IRB reviews all research projects involving research participants prior to initiation of the project. Information pertaining to application submission and full details on what is required to submit a research study are available on the UTD Office of Research Integrity and Outreach website.

6.3 Study Modification

If, during the course of the research study, the PI determines that modifications are necessary, he/she must submit the proposed changes to the IRB via CayuseIRB. Modification will be sent to the Safety Committee Chair for review. If significant modifications are proposed, including but not limited to:

- Increase/decrease in the number of study participants
- Number of scans
- Inclusion/exclusion criteria

it is within the purview of the Committee Chair to assign a review of the proposal modification. If review is required, this may result in a subsequent presentation to the full committee for decision. The Committee Chair will communicate decision results and/or approval to the PI. Decision letter(s) will be uploaded into CayuseIRB and the application will be returned to IRB analysts for further review as required.

6.4 Method Development

Method Development (sometimes called validity or pilot testing) is defined as testing a task and/or sequence in the scanner to determine whether the proposed work is feasible before finalizing a proposed study or developing a pilot study. The nature of method development 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, separate IRB approval is not required. All individuals who are scanned as part of validity testing must sign a consent form (**See Appendix C, *Consent to Participate in MRI Research*)** prior to the scan. The signed consent form will be kept on file and, if requested, a copy will be given to the individual.

PILOT Scans/Testing:

As projects move forward, pilot scans are necessary to develop & refine procedures. To be certain; however, that pilot scanning is not conducted to excess, studies should keep pilot hours to approximately four (4) hours. This practice will help BHIC maximize billable hours, ultimately keeping scanning rates low for the entire community.

7.0 Scheduling

The MRI scanner(s) scheduling is managed by the MRI Technologist, the Administrative Coordinator and/or the Research Scientist using Lab Resources Scheduler, an online resource managed by the UTD Office of Research. The Imaging Center Administrative Coordinator will provide oversight of the calendar for billing purposes. Buffer time is currently "built-in" to each scan-time reservation to allow for potential delays in participant's arrival, computer task setup, and room turnaround. Reminder emails will not be sent. Evening and weekend hours may be available upon request.

7.1 Access to Lab Resources

Access to the Lab Resources Scheduler platform requires a UTD NetID. Research staff who wish to access Lab Resources must register an account. Assignment to the Imaging

Center resources is managed by the BHIC administrators or BrainHealth IT department. Researchers should notify the Imaging Center Administrative Coordinator of IRB approval of their study/project in order to be added as a Lab Resources user.

7.2 Scan Time Reservations

Reserving a scan date and time should take place only after a participant has been properly screened & confirmed. The calendar should not be used to hold or block scanning time. The Imaging Center Administrative Coordinator and MRI Technologist should be notified as far in advance of cancellations or schedule variances so that the calendar can be updated to reflect available scan times. Reservations will be reviewed continuously to maximize the scan schedule. Violations to scheduling procedures may result in suspension of usage of BHIC scanners.

The BHIC Director, with Safety & Feasibility Committee oversight, if necessary, reserves the right to block time for high priority appointments as they relate to external deadlines, such as for grant funding or academic deadlines. The Center will work accordingly to ensure that PIs are able to have access to BHIC resources in order to manage participant scans for data collection prior to relevant deadlines or funding expiration. Similarly, graduate students with internal or external funding for projects related to their graduation requirements may be able to request priority of their scan reservation(s). Any unused blocked time will be released within 48 hours.

If a PI or MRI Operator wishes to secure an entire day on a consistent basis (e.g., one day per week), a request must be submitted, reviewed, and approved by the Operations, Safety and Feasibility Committee. The PI or MRI Operator must confirm or cancel any such reservation at least 72 hours in advance of the scheduled date and time; otherwise, the reservation will be cancelled and the date made available for general use and the PI will be billed a minimum of four (4) hours of scan time (currently, $2000).

8.0 Rules of the UTD BrainHealth Imaging Center

The UTD BrainHealth Imaging Center is a shared resource facility and, as such, researchers are expected to adhere to the procedures outlined in this manual. 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.

Everyone should be mindful of the weekly proportion of available scan time they are occupying, and work with other users to accommodate scheduling exigencies (e.g. project deadlines, participant availability, etc.) and to ensure reservations are not made more than three (3) months in advance.

If these guidelines cannot be maintained in a spirit of community and collegiality, policy changes involving weekly reservation limits, limits to calendar availability, and the like, will be implemented.

The following rules must be followed by all researchers and Operators utilizing the BHIC:

- No deviation of approved protocols is permitted unless it is specifically designated within a protocol.
- Doors to the MRI Control Room and equipment rooms must be kept closed and locked at all times. Doors to the scanner rooms must be kept closed and locked when Level 2 MR Personnel are not present.
- Access to the MRI Control Room is restricted to authorized individuals.
- Before entering the scanner room, participants & personnel must remove any objects that contain ferromagnetic material and/or may be damaged by the magnetic field.
- Any equipment to be used in the scanner room must be approved by the BHIC Operations, Safety & Feasibility Ad Hoc Committee and MRI Technologist. All equipment must be tested for ferromagnetic properties with a handheld magnet before being brought into the scanner room.
- The MRI Technologist has the authority to stop MRI procedures deemed unsafe.
- For scans involving research participants, at least one appropriately-trained MRI Operator and a second qualified attendee must be present to operate the MRI scanner.
- For scans involving human research participants, the MRI Technologist or other MRI Operator, or other research staff will:
  - Ensure participants have completed an MRI Safety Screening Form and that it has been reviewed and signed by Level 2 MR Personnel.
  - Ensure participants have signed a consent form before entering the MRI Suite, and remove any item listed in **Section 5.8** and items that are not MR-compatible (keys, cards with magnetic strips, etc.). Lockers should be used to secure participants' personal belongings and other removable items.
  - Instruct participants to refrain from crossing 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 any of the following symptoms: excessive perspiration, rapid heart rate, difficulty breathing, tightness of chest, pain or discomfort including warming of the skin, muscle tingling, etc.
  - Provide hearing protection which must be worn by research participants and any other individuals who will remain in the scanner room during the scans. The MRI Technologist or other MRI Operator shall provide hearing protection and instructions on its proper use.
  - Maintain verbal contact with the research participant during the scan.
  - Immediately investigate any research participant who does not respond to verbal contact.
  - Stop the scan if an individual becomes ill or injured. Remove the participant from the magnetic environment immediately and follow the appropriate

emergency response procedures as outlined in **Section 13.0.** All such incidents must be promptly reported to the IRB.
- Properly clean all surfaces that have come into contact with a research participant before the next MRI scan is conducted.
- Properly handle coils and all other equipment. Return all equipment to their designated storage areas.
- Report all incidents and near-misses, including equipment malfunctions, projectile accidents, security or safety breaches, or injury to personnel or research participants to PI, BHIC Director, the MRI Technologist, and the IRB.

The BHIC will maintain the most updated version of any software required for running a task during a scan. It is the responsibility of the PI/Researcher to have either the same version OR bring the appropriate hardware (laptop, tablet, etc.) to run their version of the software and to allow sufficient time to ensure proper set-up and execution of the program prior to the start of the participant scan.

After-Hours or Weekend Rules (utilizing trained independent operators)*
When MRI Operators are approved to work after-hours or during weekend hours, it should be noted that all access & safety guidelines must be adhered to accordingly. Access to the Brain Performance Institute building will be granted only to those who have completed MRI Operator Training. Other research staff who may accompany this trained individual must have also completed Level 2 MRI Safety Training and be current with CPR training.

*Operator Training is currently suspended. Inquiries regarding reinstatement of the program should be directed to the Imaging Center Administrative Coordinator or MRI Technologist.

9.0 MRI Suite Equipment Maintenance and Housekeeping

The MRI Technologist oversees scheduling of service and maintenance of the MRI Control Room and Scanners. Preventive maintenance on the scanners and chillers is conducted as requested by Siemens. Cryogenic liquid used to cool the magnet is replenished as needed. The HVAC and other supporting systems are maintained and serviced as needed.

Housekeeping duties for the control room (cleaning, sweeping and mopping floors) are the responsibility of the MRI Technologist. Floors will be swept and mopped weekly, or more frequently as needed. In addition, the scanner table must be cleaned and disinfected after every use. Blankets and linens for research participants' comfort will be laundered as necessary to ensure proper hygiene.

10.0 Considerations for Research Participants

Research participants traveling to the BHIC should be provided directions and basic information regarding the following to facilitate their visit to the BHIC:

- **Parking:** Free visitor parking is available. Researchers should ensure that participants are instructed appropriately regarding the entrance to Center for

BrainHealth vs. the entrance to the Brain Performance Institute (a map and directions are available at https://brainhealth.utdallas.edu/contact/).

- **Upon Arrival:** Participants should be instructed to wait in the lobby of the Brain Performance Institute until they can be escorted to the MRI Suite by the appropriate research staff. Research staff 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 a particular study. If the participant is running late, consideration must be made for any scans scheduled after that participant. In some cases, the participant may need to be rescheduled.
- **Confidentiality:** Procedures regarding privacy for research participants are clearly outlined by the researchers in the IRB application and it is the responsibility of the PI to ensure these procedures are followed. Names of research participants are not listed in the imaging data acquired at the scanner.

Each investigator is encouraged to examine data to ensure that the contents of the collection do not violate explicit or implicit pledges of confidentiality given to research participants. Data that could be used as identifiers should be removed, masked, or collapsed 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 work with the Office of Research to do so under a *Data Use Agreement.*

11.0 Incidental Findings

All participant consent forms must clearly state the purpose(s) of the MRI scanning being conducted, and that (1) the researchers are not medical personnel; (2) that the MRI scans are intended for research purposes only; (3) that the images produced by the BHIC MRI are not of sufficient quality for medical diagnosis; (4) the participant should not expect any clinical evaluation or review of MRI scans by medical personnel; and (5) if the MRI Technologist or researcher makes an atypical observation, a review process will be initiated.

If the researcher and/or the MRI Technologist observes something in any scan that might be an indication of an abnormality, the procedures in the *Incidental Findings Checklist* **(See Appendix D)** will be followed. The Technologist will forward the scan(s) to a consulting radiologist for evaluation. The radiologist will provide a report to the Imaging Center staff, which will then be forwarded to the PI. The PI of each study has primary responsibility to review and follow the radiologist's guidance. If the radiologist indicates that the finding is potentially significant, the PI shall report this adverse event to the IRB and notify the participant of the radiologist's guidance. No diagnosis should be provided as part of the participant notice.

12.0 Recordkeeping

Records regarding MRI safety and compliance, scan quality assurance, equipment maintenance and repair, operational hours, billing, are maintained by the MRI Technologist and/or the Imaging Center Administrative Coordinator, with oversight by the BHIC Director. A list of records is outlined below.

- Training Records: Safety and compliance training records for all personnel will be maintained by the Imaging Center Administrative Coordinator. Documentation of CPR certification and proficiency testing for MRI Operators will be stored and will be made available upon request.
- 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 will be scanned for BHIC storage and the original returned to the PI/researcher. The safety screening forms for MRI Operators, other UTD personnel, and visitors who enter the scanner room with research participants are maintained by the Imaging Center Administrative Coordinator.
- Visitor Forms: Visitors for tours of the BHIC will complete MRI Safety Screening forms which will be kept on file and maintained by the Imaging Center Administrative Coordinator.
- 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: Records of incidental findings and notifications shall be kept by the PI with the study files. These reports do not contain identifying information and will follow the naming convention for scanner files.
- Data: The naming convention for all MRI scans containing participants' data will not contain any identifying information. Per the rules and regulations of the UTD IRB, it is the jurisdiction and responsibility of the PI to keep their research participant's information protected and confidential. PIs 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.
- Equipment Performance and Maintenance Logs: The following logs are kept by the 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.
  - IP addresses, port numbers, application entry titles.
  - Participant archive log of all participants scanned.
- Scanner Usage Logs: Accurate records regarding use of the scanner are required for proper billing and reporting to federal funding agencies. When using the scanner, MRI Operators must record the following information:

- Date.
- PI overseeing the project or study.
- Study name or description.
- Type of project or study (research participant, phantom scanning, method development, pilot study, etc.).
- Participant number.
- Start and End time of scanner use.

13.0 Emergency Procedures

This section provides general emergency procedures for the BHIC. Emergencies, by their nature, are unpredictable and unexpected events that pose a potential threat to the health and safety of personnel, property, and the environment. In addition, actions to be taken in specific scenarios (removing responsive and unresponsive participants, fire, etc.) are outlined accordingly.

General Procedures

All members of the study team will be required to complete CPR and first-aid training. All attending researchers will remain free from metal and electronics (e.g., keys, watches, cell phones) during scanning. All participants will be instructed on the use of the emergency squeeze ball in the scanner. Once the squeeze ball is sounded, scanning will be ceased and efforts made to communicate and resolve the issue with the participant over the intercom. If necessary, the MRI Technologist, operator or researcher will enter the scanner room (Zone IV) to address any emergency situation that may have arisen. If the situation warrants, the participant will be removed from the scanner as quickly as possible. If a medical emergency arises, one member of the study team will call 911 while another team member will assist the scanner operator in removal of the participant from the scanner bore and the magnet room and CPR or first-aid will be administered before emergency personnel arrive.

Each emergency event will be unique and will require assessment to determine the appropriate response; however, in general, should an emergency arise, each person in the Control Room will be delegated to one of the following responsibilities:

- Stop the scan procedure (MRI Technologist ONLY)
- Assess the participant (Responsive/Unresponsive) and begin necessary emergency procedures
- Contact emergency personnel and remain available to direct responders
- Retrieve necessary emergency equipment (Defibrillator/AED; Bag Valve Mask/BVM)

The BHIC poses a hazard for emergency response personnel because they cannot safely enter the facility with typical emergency response equipment; therefore, emergency response procedures include MR safe equipment whenever possible, and procedures for removal of injured or ill individuals from the Suite by the MRI Operators. University Police and Emergency Response Team members receive training regarding hazards

associated with the BHIC and are aware not to enter the center while the magnet is operational. Additional emergency response information for the Prisma 3T magnet is available in the MRI Control Room.

13.1 Emergency Response Preparation

In preparing for emergencies in the BHIC, personnel 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 BHIC are:

- Posting Emergency Response Procedures in the MRI Control Room, along with a list of emergency contacts.
- MRI Operators and researchers are trained on Emergency Response Procedures and are periodically re-trained and updated on procedure modifications.
- A first aid kit is stocked and available in the MRI Control Room.
- MR Conditional fire extinguishers are located in the MRI Control Room.
- MRI Operators and researchers who will be in the MRI Suite while the scanner is in use must be trained in the use of fire extinguishers.
- MR Safe stretcher and wheelchair are kept in the Meadows Scanner Room.
- Two individuals must be present while the scanner is in use.
  - Level 2 MRI Safety Training and current CPR certification are required.

13.2 Emergency Notification

When an emergency situation arises, contact UTD Police by dialing 911 from any phone. 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 the emergency is in/at the BrainHealth Imaging Center in the Brain Performance Institute with **magnetic hazards**.
- 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. MRI 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:
  - Power outage
  - Fire alarm
  - Scanner console freezes (and problem is not resolved by rebooting the scanner)
  - Head coil malfunction
  - Gradient errors occur
  - Chiller malfunction
  - Any other reason deemed appropriate by the MRI Technologist

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, MRI Technologist/Operator and other trained research staff should follow these steps:

- Press the STOP SCAN button.
- Bring the table all the way out of the bore.
- Lower the table down as low as possible to the floor.
- Have the participant sit up, but do not have them get off the table right away.
- Assess the research participant.
- Do not allow anyone else to enter the scanner room unless properly screened for MR safety.
- If the symptoms subside and the participant feels better, the participant may be escorted from the facility, and a recommendation made for the participant to follow-up with a medical professional if the symptoms recur.
- If the participant is experiencing a medical emergency, the MRI Technologist/Operator will instruct other research staff to call 911 and follow emergency notification procedures in **Section 13.2**.

13.3.3 Emergency Evacuation Procedure for an Unresponsive Participant

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

- Press the STOP SCAN button.
- Instruct other research staff to call 911 from a university phone and give the operator the location
- Do not allow anyone else to enter the scanner room unless properly screened for MR safety.
- Bring the table all the way out of the bore.
- Slide the participant's head out of the coil and onto the table pad.
- Retrieve the MR safe stretcher (located in the Meadows Scanner Room) and place it next to the table, lock the wheels and maintain pressure to firmly hold the stretcher against the table.
- Using the sheet from the scanner table, roll the participant away from the stretcher, slide the white transfer board under the participant and sheet, lie the participant flat.
- Slide the participant and sheet onto the center of the transfer board and pull the board and subject onto the stretcher.
- Wheel the stretcher, with the participant on it, out of the scanner room into the Control Room.
- Close the scanner room door.
- Open the hallway door and wheel the participant out into the main corridor.
- Instruct the other research staff to obtain the AED unit.

13.4 Quench

The MRI scanner is super-cooled with liquid helium. A "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 or near zero. A quench of the magnet should only be performed by Level 2 MR Personnel or another individual if instructed to by Level 2 MR Personnel, 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 control room and emergency personnel must enter the scanner room to deal with the emergency.

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 occurs.

13.5 Fire

If a fire occurs in any of the three MRI rooms (control, scanner, or equipment room), nonferrous fire extinguishers are located in the MR Control Room to contain the fire. To ensure that researchers are familiar with using the equipment, it is strongly recommended that researchers complete the "Fire Extinguisher Course" available on the training platform, BioRAFT.

University Police have the primary responsibility for managing emergencies and must be notified immediately of such situations by calling 911 from any campus phone. Personnel are not required to fight fires and should evacuate the building immediately in the event of a fire. 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 BHIC or the building fire alarm sounds, the MRI Technologist or other Operator will:

- Stop the scan and remove the research participant as described in **Section 13.3.2**.
- Have all individuals in the BHIC evacuate the building in a calm manner and according to the building evacuation plan.
- If the fire is within the control, scanner, or equipment room, press the emergency electrical shutoff switch.
- Quench the magnet only if emergency responders must enter the scanner room to safely respond to the fire.
- Notify emergency response personnel if you have specific information about the fire and whether or not the magnet was quenched.

Appendix A – MRI Operator Competency Checklist

MRI Operator Training
COMPETENCY CHECKLIST

The following items will be observed for competency by the BHIC MRI Technologist or Research Scientist during MRI Operator Training:

☐ Participant Interaction
- Identification
- Safety screening
- Explanation of procedures

☐ MRI Safety Procedures
- Call button
- Intercom
- Cameras

☐ Emergency Response
- Patient transfer: wheelchair, stretcher
- CPR/AED
- Quench
- Evacuation, securing room

☐ Ancillary Equipment
- Projectors
- Stimulus presentation
- Button boxes, interface and modes
- Biopac
- Eye tracking
- Eye glasses

☐ Room & Participant Set-up and Positioning
- Coils: handling, mirrors
- Participant comfort: hearing protection, blanket, fan, lighting, audio
- Positioning pads
- Table operation, controls
- Landmarks, centering, adjustments
- RF/PNS management
- Scanner physio monitoring/logging

☐ Patient Registration
- ID, DOB, height, weight
- COINS requirements
- Protocol selection
- Modifications

☐ Scanning
- Sequence selection
- Slice positioning, coverage, landmarks, copy references
- Parameter modifications
- Phoenix
- Protocol management
- SAR, other warnings and potential changes
- Errors, troubleshooting
- Image QA
- Sending and saving images

☐ Documentation

☐ Image Transfer

☐ Cleaning
- Procedures updated 5/2020 due to COVID-19 (see “Re-Opening Guidelines and Procedures”)

Observation / Simulation
In addition to this complete checklist, a various amount of “shadow” scanning and “independent” scanning will be required [to be determined by MRI Technologist in conjunction with the BHIC Director].

☐ Researcher has completed sufficient observation hours AND

☐ Researcher has completed sufficient simulations to be considered an independent Operator at the BrainHealth Imaging Center.

Responsibilities/Acknowledgement:
Once trained, researchers will be responsible for Operator duties outlined in Section 8 of the “Safety Polices & Procedures Manual” as they pertain to the usage of the scanners as well as safety of the participants.

Access to the Brain Performance Institute building will be granted only to those who have completed MRI Operator Training. Other research staff who may accompany this trained individual must have also completed Level 2 MRI Safety Training and be current with CPR training.

_____ _____
Researcher Signature Date

Training completed:

_____ _____
Imaging Center Trainer Date

Appendix B – MRI Safety Screening Form

UT Dallas BrainHealth Imaging Center

MAGNETIC RESONANCE IMAGING (MRI) SAFETY SCREENING FORM

Date _____/_____/_____

Name _____ Date of Birth _____/_____/_____
Last Name First Name Middle Initial

☐ Male ☐ Female Age _____ Height _____ Weight _____

Have you ever had prior surgery or an operation of any kind? ☐ No ☐ Yes
If yes, please list:
Type of procedure: _____ Date: _____/____/_____
Type of procedure: _____ Date: _____/____/_____
Type of procedure: _____ Date: _____/____/_____

Have you experienced any problem related to a previous MRI procedure? ☐ No ☐ Yes
If yes, please describe: _____

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

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

Do you have a history of seizure disorder or epilepsy? ☐ No ☐ Yes
If yes, please describe: _____

Female Participants: Are you pregnant, or is there a possibility that you are pregnant? ☐ No ☐ Yes ☐ Post-menopausal
If yes or unsure, please notify MRI or research personnel.

Have experimenters explained all procedures involved in this study and answered all of your questions? ☐ No ☐ Yes

Have you signed a consent form explaining the procedures, your compensation, and rights as a research participant? ☐ No ☐ Yes

IMPORTANT INSTRUCTIONS

- **The powerful magnetic field of the MRI system is ALWAYS ON!**
- **Certain implants, devices or objects may be hazardous and/or interfere with the MRI procedure.**
- **Before entering the MRI room, you may be required to change into a gown and must remove all metal and electronic items including keys, hair pins, jewelry, watch, safety pins, credit cards, pens, belt, pocket knife, clothing with any metallic materials, hearing aids, cell phones and other devices.**
- **Due to high noise levels during scanning, hearing protection is required and will be provided.**
- **If you have questions or concerns, consult with MRI staff BEFORE entering the scan room.**

Do you have any of the following? Answers are required for every item below

Cardiac Pacemaker ☐ Yes ☐ No	Coronary stent ☐ Yes ☐ No
Implanted Cardioverter Defibrillator (ICD) ☐ Yes ☐ No	Heart valve replacement ☐ Yes ☐ No
Internal or external electrodes or wires ☐ Yes ☐ No	Metal or fabric mesh implants ☐ Yes ☐ No
Cardiac loop recorder ☐ Yes ☐ No	Surgical staples, clips or metallic sutures ☐ Yes ☐ No
Aortic clip, coil, stent, graft ☐ Yes ☐ No	Tattooed makeup (eyeliner, etc.) ☐ Yes ☐ No
Aneurysm clip or coil ☐ Yes ☐ No	IUD, diaphragm or pessary ☐ Yes ☐ No
Stent, filter, coil (carotid, IVC, legs, etc.) ☐ Yes ☐ No	Artificial limb or joint (hip, knee, etc.) ☐ Yes ☐ No
Metal fragments (bullet, BB, shrapnel) ☐ Yes ☐ No	Orthopedic hardware (screw, plate, etc.) ☐ Yes ☐ No
Shunt (spinal, intraventricular, VP) ☐ Yes ☐ No	Vascular access port and/or catheter ☐ Yes ☐ No
Neurostimulator (DBS, spine, bladder, etc.) ☐ Yes ☐ No	Dental hardware (braces, retainers, etc.) ☐ Yes ☐ No
Bone growth/fusion stimulator ☐ Yes ☐ No	Dentures (remove before MRI) ☐ Yes ☐ No
External insulin or other infusion pump ☐ Yes ☐ No	Hearing aid (remove before MRI) ☐ Yes ☐ No
Implanted infusion device ☐ Yes ☐ No	Medication patch (remove before MRI) ☐ Yes ☐ No
Any implant held in place/activated by a magnet ☐ Yes ☐ No	Ear/body piercings (remove before MRI) ☐ Yes ☐ No
Tissue expander (breast, etc.) ☐ Yes ☐ No	Any piercings that can't be removed ☐ Yes ☐ No
Eyelid spring, wire, weight or other eye implant ☐ Yes ☐ No	Any other items not listed ☐ Yes ☐ No
Cochlear or other ear implant ☐ Yes ☐ No	Breathing disorder ☐ Yes ☐ No
Prosthesis (eye, penile, etc.) ☐ Yes ☐ No	Movement disorder ☐ Yes ☐ No
Endoscopy capsule camera ☐ Yes ☐ No	Claustrophobia ☐ Yes ☐ No
Any other implant, even if no longer active ☐ Yes ☐ No	Anxiety ☐ Yes ☐ No

Please provide details regarding any question(s) answered YES above: _____

_____

_____

_____

_____

_____

I attest that the information I provided on this form is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information and the MRI procedure that I am participating in.

Form completed by ☐ Participant ☐ Other (specify relation) _____

Printed name of person completing form _____

Signature of person completing form _____ Date _____/_____/_____

For MRI personnel use

Form reviewed by Level 2 MR Personnel:

Print Name/Title _____

Signature _____ Date _____/_____/_____

Appendix C – MRI Protocol Testing Consent Form

University of Texas at Dallas

CONSENT TO PARTICIPATE IN MRI RESEARCH

Title of Research Project: Human Subjects Pulse Sequence Testing and Calibration

Investigators:	**Contact Number**
Principal Investigator: Bart Rypma, Ph.D.	972-883-4472
Co-Principal Investigator: Jason Grubb	972-883-3472
Research Assistant: Angela Plata	972-883-3355

Purpose: This study is being done to fine-tune the scanning protocols for use in imaging studies.

Description of Project: The opportunity to scan human volunteers will allow us to identify potential issues and perform adjustments to confirm that our equipment, procedures, and scans are ready for use in our upcoming studies. Please note, Siemens service engineers have performed their testing and have approved the scanners for use, but human scanning is needed to help fine-tune the scans as there are differences between scanners and sites. Imaging centers routinely provide volunteers from their staff for these scanning sessions for quality assurance.

Only standard MR pulse sequences will be used for these volunteer scans. They are scans provided by Siemens and used routinely throughout clinical and research imaging centers.

The length of time spent by each volunteer in the scanner will vary based on the scans under evaluation and the volunteers' abilities and availabilities. Volunteers will likely be in the scanner from 15 minutes to one hour but the tests will be stopped immediately upon any volunteer's request.

Number of Participants: About 20 people will take part in this study at UT Dallas Brain Performance Institute.

Procedures during the research: During this experiment, you will have an MRI. MRI is a noninvasive imaging technology used to generate images of a participant's brain. Researchers then use these images of brain activity to gain an understanding of the activity of the brain. For most of this procedure, you will lie quietly while trying not to move inside a large, doughnut-shaped magnet for 15 to 60 minutes. The time spent will be based on your feedback of availability to the researcher. There are two possible tasks you might be asked to do during this time. For the first, there will be screen in front of you with words, and you will be asked to make judgments about these words and

respond by pressing a button. For the second, you might also be asked to press a button in a certain rhythm. The researcher will instruct you verbally over the intercom during these tasks. If you are not asked to perform a task, you will be able to rest quietly with your eyes closed.

Possible Risks:
Because of your participation in this study, you are at risk for the following side effects:

- There are no known long-term effects from exposure to magnetic fields.
- The MRI machine imager makes a loud, banging noise while it is taking pictures. You will be given and asked to wear a set of earplugs and/or protective headphones to help reduce the noise.
- You may experience nervousness from confinement in a tight space (claustrophobia). If you become anxious or nervous, you can stop the procedure at any time.
- You may experience some discomfort, and fatigue from lying still during the imaging. Some subjects also experience dizziness upon sitting up.
- If you have any metal in or on your body that is non-removable, you should tell the investigator.
- If you have metal in or on your body that is non-removable, that has not been disclosed, this metal could move or shift while you are in the MRI machine and possibly cause injury.

MRI may not be appropriate if you have permanent make-up, artificial eyebrows or lashes, or any pieces of metal in your body, such as the following:

- heart pacemaker, heart valve replacement, or aortic clips
- metal fragments in your eyes, skin, or elsewhere in your body
- brain clips or pieces of metal used in aneurysm surgery or intracranial bypass
- venous umbrella
- pieces of metal in the body resulting from work as a sheet-metal worker or welder
- clips placed in an internal organ
- prosthetic devices, such as middle ear, eye, joint, or penile implants
- joint replacement
- hearing aid that cannot be removed
- neurostimulator
- insulin pump
- intrauterine device (IUD)
- shunts or stents
- metal mesh or coil implants
- metal plate, pin, screws, or wires, or any other metal implants

Other rare, but possible, risks of MRI: 1) Neurostimulation. In some cases, it is possible that the subject might experience neurostimulation effects (muscle twitches and tingling sensations, due to the rapid switching of magnetic field gradients used in these examinations). The effect maybe exaggerated if the subject creates a connected pathway with their body by crossing their legs, linking their hands, crossing their arms and so on. Subjects will be asked not to create a connected pathway so to minimize these effects. It is known that neurostimulation effects may, in rare occasions, cause RF burns that maybe either internal or external. 2) Quench Hazard. The MR scanner uses liquid nitrogen and liquid helium. It is remotely possible that the liquid nitrogen and helium will boil off rapidly and fill the magnet room with extremely cold, dense, gaseous nitrogen and helium, which can be dangerous if breathed for more than a few moments. The scanner operator will obviously detect a scanner quench and immediately provide assistance to anyone inside the magnet room by removing them as quickly as possible.

Females:
If you are part of this study while pregnant, it is possible that you may expose the unborn child to risks. For that reason, it has been decided by the researchers that pregnant women cannot participate in the study.

COVID-19 Information:
The novel coronavirus, COVID-19, has been declared a worldwide pandemic by the World Health Organization. COVID-19 is extremely contagious and is believed to spread by the kind of person-to-person contact that you may engage in by participating in this research study. Thus, as with any activity involving person-to-person contact, there is a risk that you might contract the virus and expose other individuals that you might come in contact with after participation in this study. Older adults and people of any age who have serious underlying medical conditions like heart disease, diabetes, cancer, or a weakened immune system, are at a higher risk for getting very sick from COVID-19.

In consideration of these risks, investigators are taking extra precautions based on recommendations of the Center for Disease Control. If you have questions about the safety measures that are in place, the investigators can provide you with this information. These measures have been approved by the Institutional Review Board.

Questionnaires to Assess COVID-19 Symptoms and Exposure: The investigators will be conducting pre-screening (before the in-person visit) and post-screening (after the in-person visit) questionnaires to assess your symptoms and exposure to COVID-19. The pre-screening questionnaire will be completed approximately 24 hours before the in-person visit, and the post-screening questionnaires will be completed approximately **5 days and 14 days after** the in-person visit. If you experience any symptoms related to COVID-19 or receive positive test results, you are strongly encouraged to contact the investigators or the IRB Office.

Your Confidentiality in the Case of Infection: If a participant tests positive for COVID-19, investigators may be required to notify local health authorities that you have been on the UTD Campus. If investigators have to report this, they will only provide the minimum information necessary and will not provide any details about the reason(s) for the participant's visit. By signing this form, you are agreeing that the investigator may do so without an additional signed release.

Possible Benefits to the Participant: If you agree to take part in this study, there are no direct benefits to you, except for the experience of participating in the study.

Alternatives to Participation: Individuals may choose not to participate.

Payments to Participate:
Participants will not receive any reimbursement for participation in this study.

Voluntary Participation: All individuals have the right to agree or refuse to participate in this study. Individuals who consent to participate also have the right to change their minds while experiencing the experimental procedure. Participants may tell the investigator that they no longer wish to participate. Refusal or withdrawal of participation will not involve any penalty or loss of benefits to which non-participants are entitled. Refusal to participate will not affect participants' legal rights.

Records of Participation in this Research:
Information Stored at the University of Texas at Dallas
All of the information participants provide to investigators as part of this research will be protected and held in confidence within the limits of the law and institutional regulation.

- Your data collected will be given a code number to be used for research identification, and your name will be kept anonymous.
- All identifiable data, along with consent forms, will be kept in a locked cabinet.
- Only the investigators of this study will have access to your identification.

Information Available to Others:
Members and associated staff of the Institutional Review Board (IRB) of the University of Texas at Dallas may review the records of your participation in this research. An IRB is a group of people who are responsible for assuring the community that the rights of participants in research are respected. A representative of the UTD IRB may contact you to gather information about your participation in this research. If you wish, you may refuse to answer questions the representative of the IRB may ask.

Publications Associated with this Research: No publications will be made based on this research.

Contact People:
Participants who want more information about this research may contact any of the investigators listed at the top of page 1 of this document. Participants who want more information about their rights as a participant or who want to report a research related injury may contact:

The University of Texas at Dallas Institutional Review Board 972-883-4579
UTD Office of Research

Signatures
A participant's signature indicates that they have read, or listened to, the information provided above and that they have received answers to their questions. The signature also indicates that they have freely decided to participate in this research and that they know they have not given up any of their legal rights.

_____
Participant's Name (printed)

_____ _____
Participant's Signature Date

_____
Name of Researcher Obtaining Consent

_____ _____
Signature of Researcher Obtaining Consent Date

Appendix D – Incidental Findings Checklist

IMAGING CENTER
INCIDENTAL FINDING/ATYPICAL OBSERVATION
REPORTING CHECKLIST

Should an atypical observation on an MRI Image be identified, these steps should be followed:

- ☐ RESEARCHER should inform MRI TECHNOLOGIST and Research Scientist of the atypical observation
- ☐ Technologist will document observations in an email to be communicated to Consulting NEURORADIOLOGIST and ADMINISTRATIVE COORDINATOR (with oversight from DIRECTOR)
- ☐ Neuroradiologist reads & provides report of findings within 24 hours to Administrative Coordinator
- ☐ Administrative Coordinator will provide report back to PI/Researcher and UTD IRB office
  If advised by Neuroradiologist report, study PI will forward the report to the study participant with instructions to follow-up with their primary care physician

  As required by IRB regulations, Administrative Coordinator will notify IRB office of the atypical observation by way of email (Neuroradiologist report will be provided)
- ☐ Final report will be saved in secure folder accessible only by Imaging Center staff including Director, Administrative Coordinator, and Technologists

SUPPLEMENTAL MATERIALS*
(COVID related)

Re-Opening Guidelines and Procedures
Health Screening Questionnaire
Reservations & Access Guidelines
COVID-19 Information Sheet
COVID-19 Re-Opening Best Practices
"Request for Variance" Form

*In March, 2020, due to the Coronavirus/COVID-19 pandemic, UTD Office of Research shut down in-person human subject research. The BrainHealth Imaging Center suspended operations effective March 16, 2020. The "Re-Opening Guidelines and Procedures" were developed by the Imaging Center Director & staff, and vetted by the MRI Executive Advisory Board and Operations, Safety & Feasibility Ad Hoc Committee, to provide the safest methods of scanning for research staff and participants for use as various phases of human subject research resumes.

THE UNIVERSITY OF TEXAS AT DALLAS
BRAINHEALTH®
IMAGING CENTER

UTD BrainHealth Imaging Center
Re-opening Guidelines and Procedures

PREFACE:

The state, the country, and UTD itself have all moved toward re-opening. We too have been working through what reopening looks like at the UTD BrainHealth Imaging Center (BHIC). In developing our strategy, we have followed guidance from available national & local resources such as the CDC, the UTD Office of Research, and our colleagues at the AIRC. We are also continuing to be mindful of local incidence rates and actively monitoring the daily UTSW COVID-19 admissions in order to assist us going forward.

The following protocols for participant entry, pre-scan preparations, scanning guidelines and post-scan procedures including but not limited to participant exiting, disinfecting & sanitizing scan/work areas as well as PPE waste disposal were developed with the ultimate goal, as always, to minimize the risks to staff and participants coming to the Imaging Center.

UTD's Office of Research announced that as of October 12, 2020, Human Subject Research (HSR) could resume. The Center still anticipates an initial low throughput (up to 4 scans per day). This continues to take into account "method development" studies that will include non-general population participants (i.e. limited, designated lab personnel).

COVID TESTING:

With the resumption of HSR, the Office of Research began providing COVID testing to designated researchers who will be resuming in-person human subject research. BHIC will welcome two (2) researchers into the center for training and scanning who have 1) been designated and 2) who have received a bi-weekly negative test result.

For the safety of our staff, BHIC will limit personnel to two (2) per lab in an effort to keep a limited number of people coming through the center.

Scan-Time Reservations:

Lab Resources reservations for participant scans will remain "pending" until bi-weekly negative test results have been documented. **Individual researchers are responsible for notifying the Administrative Coordinator of their results.**

If your study requires a variance to any of the following procedures, please submit a "Request for Variance" that will be reviewed by the MRI Operations, Safety & Feasibility Committee.

GENERAL PROCEDURES:

- Within 24 hours of the study visit Researchers will pre-screen all Participants using the UTD BHIC "MRI Safety Screening Form" and "Infectious Disease Screening Questionnaire."

- Six (6) feet social/physical distance rule within the Imaging Center will be in force at all times.

- Anyone entering the BHIC will be required to wear face masks at all times.

- Hand sanitizer will be readily available and will be required upon entering & exiting the Imaging Center.

- Participants should be instructed to bring minimal personal items, jewelry, etc.

- Participants should be informed about the use of an alternate entrance being utilized at the Brain Performance Institute. Researcher should guide/direct Participant to park closest to the Betty & Joel Williams, Jr. Garden entrance.

- Participants should be informed regarding the required use of PPE (masks, scrubs, head coverings, non-skid socks) while in the Imaging Center.

- One (1) hour will be blocked between visits to allow for cleaning (described below in the "Cleaning Procedures" section).
  - Includes sanitizing used areas and set-up equipment for next scan (allowing sufficient air exchange in the Scanner Room and scanner bore).

- The Brain Reset Room, Testing/Consent Room, etc. will not be available for use.

- Pre or Post-task assessment can be accommodated in Room 1.5C1.
  - Should be kept to a minimum so as not to increase exposure/risk.
  - Researchers will be responsible for cleaning/sanitizing this area following scan or post-task procedures.

- A single occupancy restroom will be available prior to entry to the Imaging Center. Use of the restroom within BHIC is strongly discouraged, but available if needed.

- Personnel inside the Control Room will be limited to:
  - Scanner Operator
  - One Researcher
    - Designated personnel will be limited to TWO (2) per lab
    - Researcher will undergo specific training regarding:
      - Proper donning & doffing of PPE
      - Participant set up in & exit from the scanner
  - One Participant

- Six (6) feet social/physical distance within the Control Room will be required.

- Anyone remaining in the Control Room will be required to wear a face mask, except the Participants while in the scanner (detailed instructions will be provided to the Participant about when/if to remove their mask).

- Everyone will use hand sanitizer upon removing gloves or touching door handles, etc.

VISIT PROCEDURES:

- Participant arrives at the BrainHealth complex and calls the Researcher conducting the experiment.
  - Researcher should direct Participant to parking area closest to the garden entrance.
  - Researcher (wearing face mask) will meet Participant in the parking lot.
  - Participant should arrive wearing a face covering/mask (disposable or cloth).
  - If Participant arrives without a face covering/mask, they will be provided a face-mask to wear into the Imaging Center.

- Researcher will:
  - Escort Participant through garden entrance to perform re-screening.
  - Re-screen Participant using the BHIC Infectious Disease Health Questionnaire (scan will only proceed if responses are still clear).
    - A hard copy of the Infectious Disease Health Questionnaire must be provided to the MRI Technologist prior to the start of the participant scan.
  - Take Participant temperature.
    - If temperature is below 99.5, they will then contact the Scanner Operator that they are ready to enter the Imaging Center.
    - If temperature is above 99.5, the scan will not be performed and the Participant will work with the Researcher to reschedule.

- If necessary for access to the Center, Scanner Operator (wearing face mask) will meet Researcher & Participant at the designated alternate entrance of Imaging Center.

- Participant will be escorted to the changing area to remove and secure any personal items.

- Participant will be asked to don disposable scrubs over their street clothes. If clothing is too restrictive for movement as required inside the scanner, the participant will have the option to change from street clothes into scrubs, securing clothing in a locker.
  - If Participant has entered with their own face covering, they will be instructed to change into the face-mask provided by the Imaging Center (available in the changing area).

- Participant should be instructed to remove street shoes. If preferred, they can don disposable non-skid socks available in the changing room.

- As Participant is in the changing area, Researcher will don PPE (disposable shoe coverings, disposable isolation gown, gloves & face shield).

- Once inside the Control Room, Scanner Operator will review the MR Safety Screening Form with participant (no deviation from normal practice).

- Researcher will escort Participant into the scanner room and position them on the table according to the ENTRY checklist (as per training & as posted within the scanner room).
  - Contact with the Participant will be kept at a minimum during the positioning phase.
  - Researcher will leave face shield in scanner room.

- Researcher will secure room, remove & dispose of gloves & gown, and apply hand sanitizer.

- Scanner Operator and Researcher will maintain 6 feet of social/physical distance in Control Room during the experiment.
  - As much as is feasible, equipment will be moved so that Operator & Researcher avoid facing each other.
  - If equipment cannot be moved to keep safe physical distance, the Operator will step away from the console to allow the Researcher to complete necessary tasks.

- At the end of the experiment, the Researcher will put on gloves & gown prior to re-entering the scanner room.
  - Prior to approaching Participant, Researcher will replace face-shield.

- Researcher will remove Participant from scanner according to the EXIT checklist (as per training & as posted within the scanner room) and, if necessary, provide them a face mask.
  - Participant must be wearing their face mask prior to exiting the scanner room.
  - Participant will be asked to wear their mask until they exit the building.
  - Researcher will escort the Participant out of the scanner room.

- Researcher will escort Participant to the changing area to retrieve personal items.

- Participant will be asked/instructed to remove scrubs and discard them in the proper container.

- OPTION 1: Researcher will escort Participant to 1.5C1 for post-task assessment.

- OPTION 2: Participant will be escorted back to the garden area in order to exit the building.

- Researchers will be return to 1.5C1 for cleaning/sanitizing this area following scan or post-task procedures.

CLEANING PROCEDURES:
All cleaning procedures will follow the product manufacturers' instructions for application, contact time, etc.

Products used:
Peroxigard disposable disinfectant wipes
Peroxigard disinfectant spray and paper towels

- Scanner Room
  - Scanner: table, head coil, inside of bore (using an extender [e.g. plastic "swiffer type"] mop), front panels and controls.
  - Accessories: positioning pads, button boxes, call button, audio headset, etc.
  - All door handles, cords, and other surfaces used or potentially touched.

- Control Room
  - All door handles, scanner intercom unit, projector controls, counters, computer and computer accessories (keyboards, mice, etc.), desks, chairs, etc.

- Changing Area
  - Chairs, locker (inside and out), lock, key, door handles, cabinets, tables, etc.

- Screening Area
  - All door handles between garden entrance and Imaging Center entrance (including restrooms as needed).

- Pre/Post Testing Room
  - All door handles, storage cart, thermometer, pens, and other surfaces used or potentially touched.

- Other
  - Floors and paths used between the Imaging Center entrance and the scanner.
  - All surfaces in Imaging Center restroom as needed.
  - At regular intervals, disposable PPE will be gathered and moved to the outside trash bin.

THE UNIVERSITY OF TEXAS AT DALLAS
BRAINHEALTH®
IMAGING CENTER

UT Dallas BrainHealth Imaging Center
Infectious Disease Screening Questionnaire

Screening Date:	Confirmation by MRI Date:
Participant ID:	Confirmed by:

Do NOT schedule or scan anyone who answers "Yes"

1. In the last 14 days, have you traveled anywhere abroad or to a Level 3 area (including China, Iran, Italy, UK, Ireland, or Brazil) OR any cruise? ☐ **Yes** ☐ **No**

2. In the last 14 days, have you traveled outside the State of Texas? ☐ **Yes** ☐ **No**

3. In the last 14 days, have you come into contact with a person with COVID-19 or other infectious disease? ☐ **Yes** ☐ **No**

4. In the last 14 days, have you been in a gathering (indoor restaurant, bar, church, gym) of 5 or more people who are not members of your immediate household where social distancing (less than 6 feet, no masking) was NOT practiced? ☐ **Yes** ☐ **No**

5. In the last 14 days, have you experienced any of the following new or worsening symptoms, in a way that is not normal for you:

Y / N		Y / N	
☐	☐ Fever (greater than 99.5)	☐	☐ Sore Throat
☐	☐ Cough	☐	☐ Muscle Aches
☐	☐ Shortness of Breath	☐	☐ Pneumonia
☐	☐ Chills	☐	☐ Diarrhea
☐	☐ Extreme Fatigue	☐	☐ Vomiting
☐	☐ Severe Headache	☐	☐ Loss of sense of smell or taste

ARRIVING AT THE UTD BRAINHEALTH IMAGING CENTER

Participants will enter the BrainHealth complex and park near the South fence-line.

To minimize traffic into public areas, Researchers will lead participants through the Betty & Joel Williams, Jr. Garden entrance just adjacent to the main entrance of the Brain Performance Institute.

ENTERING THE UTD BRAINHEALTH IMAGING CENTER

Participants will be re-screened and will have temperature taken prior to entering the BrainHealth Imaging Center.

Once cleared, Researcher can:

proceed with Participant to the appropriate pre-task assessment area for pre-scan testing (this should be kept to a minimum so as not to increase exposure risk)
OR
escort Participant through the prescribed route (see map below) to the entrance of the Imaging Center (★)

EXITING THE UTD BRAINHEALTH IMAGING CENTER

Upon completion of scanning procedure, the Researcher & Participant will exit the Imaging Center using the same route in which they entered.

Researcher can:

return with Participant to appropriate post-task assessment area for necessary post-scan testing (this should be kept to a minimum so as not to increase exposure risk)
OR
escort Participant to exit of Brain Performance Institute

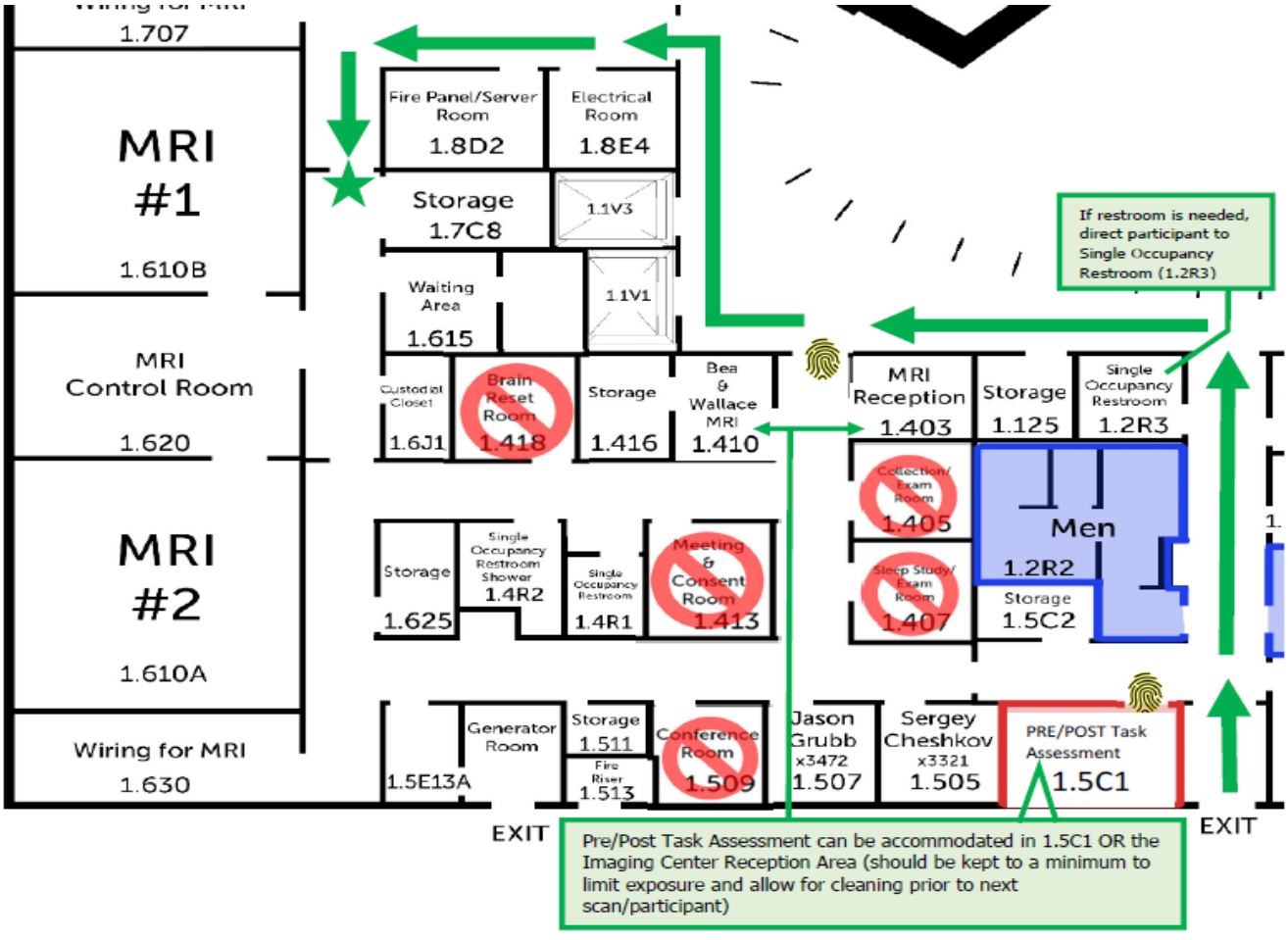
Researcher will be responsible for disinfecting/sanitizing the pre/post task assessment room(s) (1.5C1 or 1.403) after Participant has exited/completed post-scan testing.

PARTICIPANT ENTRANCE TO/EXIT FROM THE UTD BRAINHEALTH IMAGING CENTER

Use Betty & Joel Williams, Jr. Garden Entrance

Re-screen/temperate check point in foyer

Traverse through lobby (be mindful of keeping to the course outlined)



RESERVING TIME AT THE UTD BRAINHEALTH IMAGING CENTER

Similar to scheduling lab time on campus, the UTD BrainHealth Imaging Center will be utilizing Lab Resources Scheduler to reserve time on the scanners. During this transition, no other rooms (brain reset, training, or consent) will be accessible in the MRI Suite.

PIs must designate which personnel will be eligible to return to conduct research by completing this form. Upon completion of the form, they will receive confirmation from the Office of Research along with a PDF version of the completed survey.

THIS FORM MUST BE FORWARDED/SUBMITTED TO THE BRAINHEALTH IMAGING CENTER ADMINISTRATIVE COORDINATOR, Angela Plata.

Designated personnel will be given access to the imaging center resources after receipt of this form and completion of the required UTD training & certification as well as the appropriate level of MRI Safety training (including CPR certification).

Confidential

Record ID 183
Page 1

Elect Personnel

During this phase, undergraduate personnel are not permitted to return to campus research activities. InstructionsEnter personnel details. PIs should not add themselves.Click the button that says "Add Another Person" to add another person. Repeat this step to continue adding personnel.Once you've added all the personnel desired, click the button "Continue".

Response was added on 05/26/2020 1:38pm.

PI Name: Bart Rypma

Individual Personnel Information	
Date	05-26-2020 13:20

Type to search the UT Dallas Directory, then click on the appropriate personnel from the drop-down. If you cannot locate, please enter information manually.

Personnel Name

Angela Plata

Personnel NetID

amp190011

Personnel Email

amp190011@utdallas.edu

Personnel Location

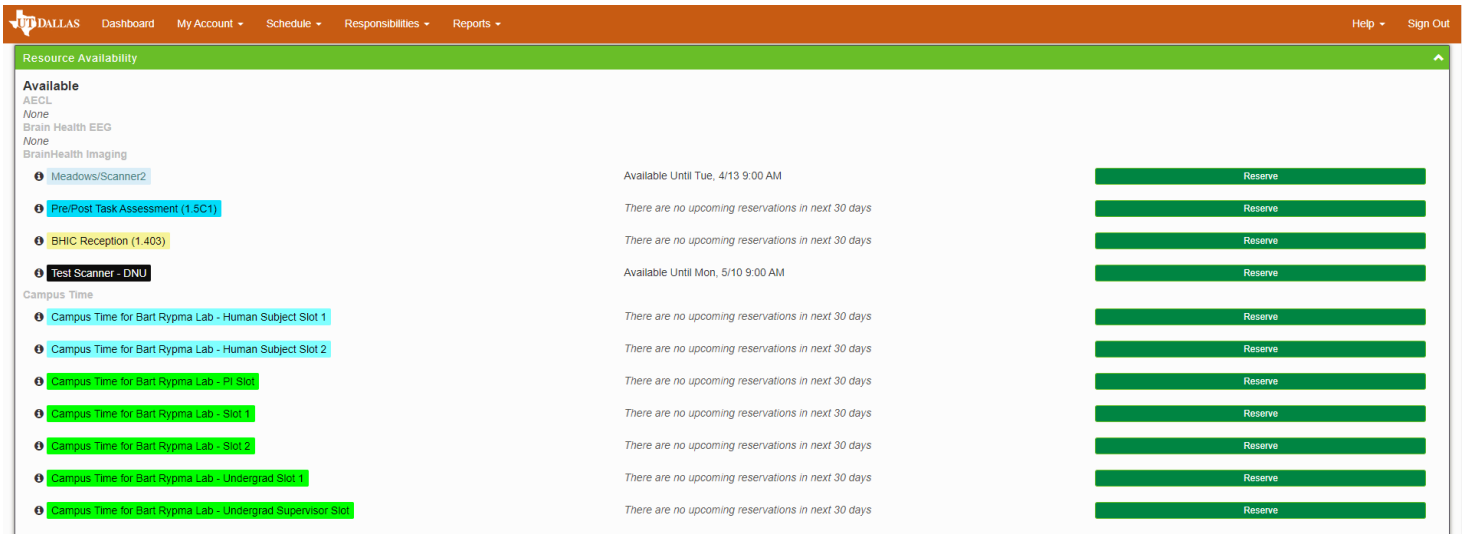
CBH2.426
(Examples: BSB 2.304, NSERL, Hearing Health Lab)

Researcher PI Name	Bart Rypma
Researcher PI NetID	bpr061000
Researcher PI Email	bpr061000@utdallas.edu

Lab Resources Scheduler

RESERVE SCANNER TIME

Lab Resources Scheduler requires NetID and password for log-in. Personnel will see the availability of resources (ex: Meadows/Scanner 2) that have been granted to them to create reservations.



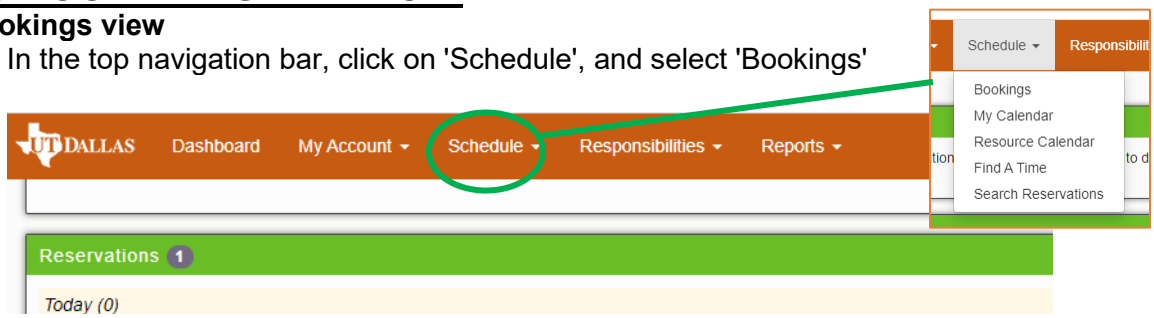
Reservation Rules

- **Effective April, 2021 >** Scan time reservations have been DECOUPLED from pre/post task assessment time. Additional "resources"/schedules have been added to Lab Resources.
- Scanner reservations should account for participant change time, researcher donning/doffing of PPE, participant set-up time AND study scan.
  - In adherence to physical distancing and disinfecting protocols (including sufficient air circulation), a 60-minute buffer is automatically added between scanner reservations.
- Billing is based on actual scan-time as marked in the scanner log (no deviation from previous procedure); HOWEVER, please make sure you are as efficient as possible when entering & exiting for your scanner time reservation to ensure no participant overlap.
- **Reservations MUST include:**
  - Title > project abbreviation (ex: MJX, BHP, JWR, fMRI, ViCTOR) AND a unique participant ID (this will be key for tracking, cancellations, reschedules, second time point scans, billing, etc.).
  - Description > Participant ID; how data will be stored (COINS or user-supplied external hard drive); additional set-up requirements OR equipment use
  - PI
  - Cost Center (required for billing purposes)
  - Scanner to be used (required) > while we are running 1 scanner at a time, please select which scanner to be used/set-up
  - Guide > name of researcher bringing participant to BHIC (this could be the person making the reservation OR other staff name if others are responsible for booking reservations)
  - Project/IRB Number
- Pre/Post Task Assessment reservations can be made in the **Pre/Post Task Assessment Area (Room 1.5C1)** AND/OR the **Imaging Center Reception area (Room 1.403)**. Both areas should be disinfected by the researcher after each use.
  - To ensure no participant overlap and to account for any delay in scan time, there is a 30-minute buffer added between pre/post-task assessment reservations.

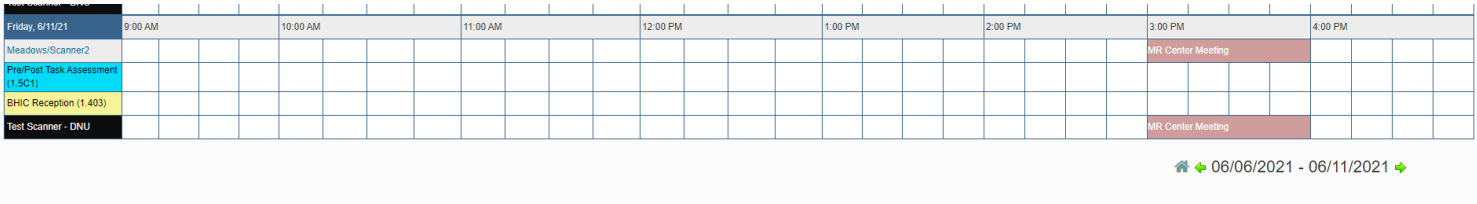
TO BOOK A RESERVATION:

Bookings view

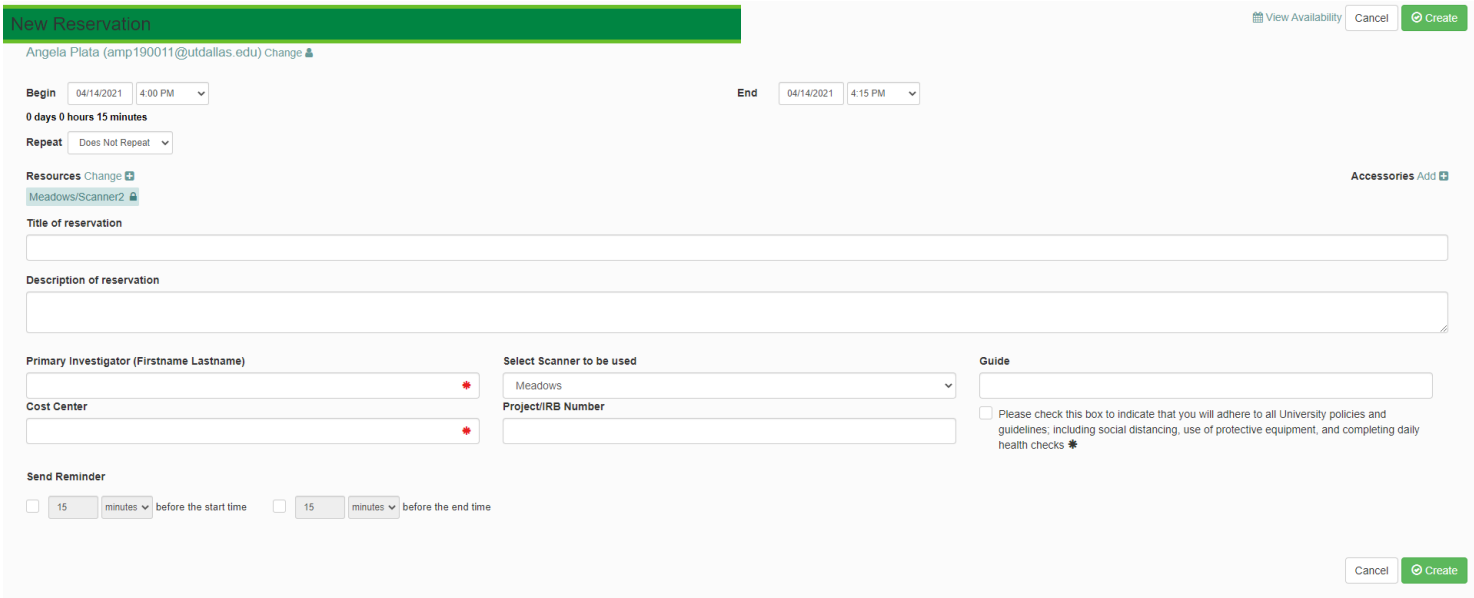
1. In the top navigation bar, click on 'Schedule', and select 'Bookings'



This view is akin to a gantt chart. Click on the calendar icon, or the green arrows, to adjust the date timeframe.



2. Click on an “open” time slot and fill out the reservation form (*note: click and drag to select a longer period of time OR adjust the time in the reservation form).



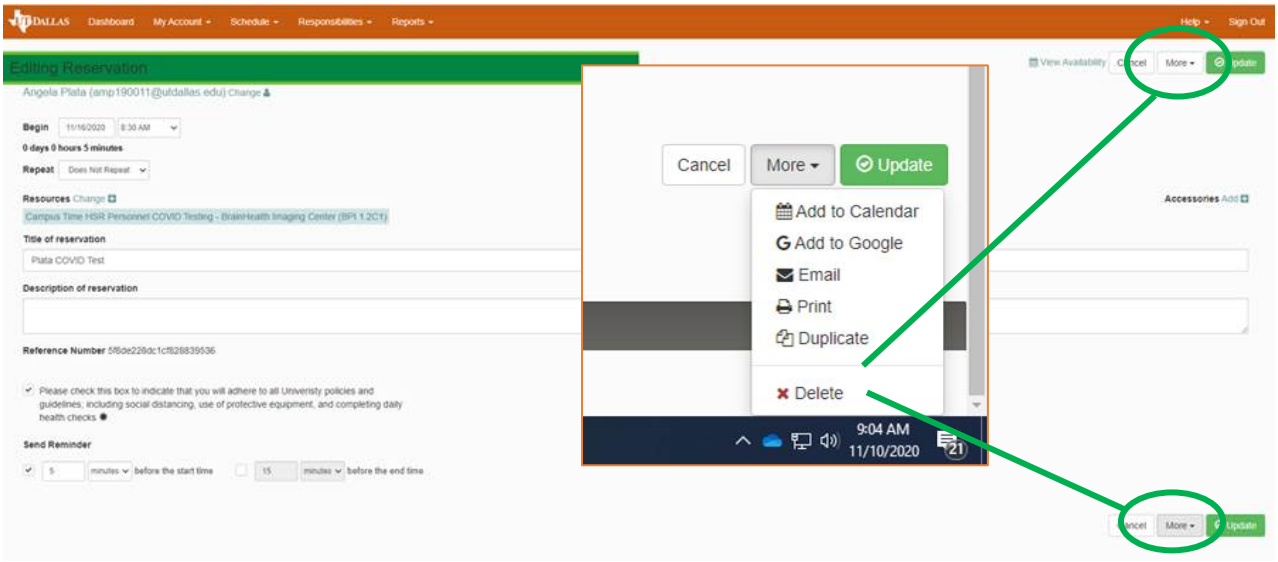
Researchers (guides) are responsible for providing weekly negative COVID test results to the Administrative Coordinator in order for scanner reservations to be approved.

Pre/Post Task Assessment reservations will be monitored but not approved by the Imaging Center.

How to remove a reservation in Lab Resources

Reservations can be seen on the homepage “Dashboard” OR from the “Bookings” view.
Click on the reservation to enter “editing” mode.

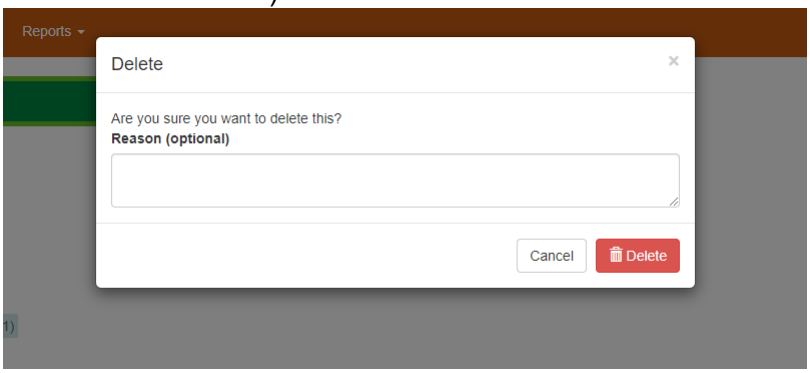
Click “More” in order to DELETE



Once “Delete” is selected, a description box becomes available.

PLEASE ENTER A REASON FOR THE DELETION

(“Participant XX called to cancel their appointment / has been rescheduled / will be rescheduled”)



Click “Delete” > sends a notification to resource/schedule administrators.

[Visit the Office of Research Wiki page for step-by-step how-to guides.]

THE UNIVERSITY OF TEXAS AT DALLAS
BRAINHEALTH®
IMAGING CENTER

COVID-19 INFORMATION SHEET FOR RESEARCH PARTICIPATION

At the UTD BrainHealth Imaging Center, our primary responsibility related to research is to protect the safety of our research participants.

COVID-19 refers to the coronavirus that is being spread across people in our communities. It is important that you consider the following information to determine if study participation is right for you.

How is COVID-19 spread?

- Mainly from person-to-person in close proximity or airborne droplets – especially indoors
- Touching a surface or object (such as a doorknob or other counter surface) that has the virus on it, then touching the mouth, nose or eyes

Can COVID-19 be prevented?

At this time, there is no vaccination but the risks of exposure can be reduced by:

- Avoiding large gatherings
- Stay at least 6 feet away from others
- Refraining from shaking hands with others
- Washing or disinfecting hands regularly
- Wearing a mask or appropriate cloth covering over the nose and mouth
- Wearing glasses or a plastic face shield
- Keeping rooms well ventilated

What are the risks of COVID-19?

- For most people, only mild or moderate symptoms, such as fever and cough.
- For some, especially older adults and people with existing health problems, it can cause more severe illness, including pneumonia, embolic events or systemic inflammations.
- For a few, it can result in death.

What are the risk factors for serious illness with COVID-19?

- Asthma
- Chronic lung disease (i.e. COPD)
- Chronic kidney disease being treated w/dialysis
- Diabetes
- Hemoglobin disorders
- Recent embolic incidence
- Serious heart conditions (i.e. recent heart attack, hypertrophy, atrial fibrillation)
- Immunocompromised
- Liver disease
- Severe obesity
- Aged 65 years and older
- Live in nursing home or long-term facility

What is BHIC doing to minimize risk?

- Separate building entry for research participants to avoid contact with general/employee areas
- Health screening and COVID questionnaire before arrival and before entry into the building
- Masks for research participants and accompanying persons, study researchers, scanner operators
- Additional protection gear for researchers (gloves, gowns, face shield)
- Hand sanitizing before entering the center, changing room, and MRI scanner room
- Frequent disinfection of commonly used surfaces including inside changing room
- Thorough disinfection of MRI scanner before and after each scan
- Limiting number of people in MRI suite and MRI console room [Operator, Researcher, Participant]
- Adding additional time between scans

The information related to risks of COVID-19 changes every day. The leaders at UTD are monitoring these risks and deciding how these risks should change our research. If you have questions about COVID-19 and your participation in research, please talk to your study team. You can decide against participating at any time.

Following your scan, should you develop any symptoms listed above, please contact your study team.

UT Dallas BrainHealth Imaging Center

COVID-19 Re-Opening Best Practices

To minimize the risk to public health while performing research at the UT Dallas BrainHealth Imaging Center, staff/researchers are expected to adhere to public health practices to minimize the spread of COVID-19.

NAME: _____

NetID: _____

Personnel, to the best of their ability, will adhere to the following public health behaviors:

☐ I will limit my exposure to COVID-19 by maintaining social distancing guidelines while utilizing the BrainHealth Imaging Center.

☐ I will wear the appropriate personal protective equipment and practice proper handwashing techniques frequently.

☐ I agree to closely monitor my health and will not participate in face-to-face research activities if I develop or display symptoms of COVID-19 including but not limited to fever, dry cough, chills, headache, loss of taste or smell, muscle pain, sore throat, and new GI symptoms (nausea, vomiting, diarrhea).

☐ I agree that I will not participate in face-to-face research activities, and will notify appropriate university personnel if I become aware that I have been exposed to someone who has tested positive for COVID-19.

☐ I will comply with the policies and procedures established by my PI, laboratory or research team and will comply with the procedures in the BrainHealth Imaging Center used for my research.

By signing, I understand that I have a responsibility to respect and comply with the best practices & guidelines described above.

I understand my failure to comply can result in my suspension from research activities at the BrainHealth Imaging Center.

_____ _____

Signature Date

THE UNIVERSITY OF TEXAS AT DALLAS
BRAINHEALTH®
IMAGING CENTER

Request for Variance

Describe in detail the point in the standard procedures where your study will require a variance from the UTD BHIC Re-opening Guidelines and Procedures.

Variances to UTD, Office of Research, or CDC guidelines in relation to face coverings or social/physical distancing will not be permitted. Only limited variances will be considered.

GENERAL PROCEDURES:

Identify the specific part of the Imaging Center procedure you want to vary.
(describe each OR indicate N/A if no variance is requested)

Click or tap here to enter text.

Describe in detail how your procedure will vary.
(describe each OR indicate N/A if no variance is requested)

Click or tap here to enter text.

VISIT PROCEDURES:

Identify the specific part of the Imaging Center procedure you want to vary.
(describe EACH procedure where a variance is requested)

Click or tap here to enter text.

Describe in detail how your procedure will vary.
(describe EACH procedure where a variance is requested)

Click or tap here to enter text.

JUSTIFICATION:

Provide a detailed justification for the variance you are requesting.

Click or tap here to enter text.