JOINT MR RESEARCH SAFETY MANUAL

COLUMBIA UNIVERSITY

NEWYORK-PRESBYTERIAN HOSPITAL

NEW YORK STATE PSYCHIATRIC INSTITUTE

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I. INTRODUCTION AND OVERVIEW

A. Purpose of the Manual

The purpose of this Joint MR Research Safety Manual (this **Manual**) is to provide an overview of the safety program (the **MR Research Safety Program)** for magnetic resonance imaging (**MR**) used in research at Columbia University (**Columbia** or the **University),** the Columbia University Irving Medical Center campus of NewYork-Presbyterian Hospital (**NYPH)** and New York State Psychiatric Institute (**NYSPI**) (collectively, the **Program Institutions)**. The MR Research Safety Program is a joint tri-institutional program responsible for assisting the Program Institutions in the safe use of MR and the protection of staff, research subjects and the general public from the risks associated with MR.

The MR Research Safety Program has three components covering: (1) the University, including (a) the Zuckerman Mind Brain Behavior Institute (**ZMBBI)** on Columbia's Manhattanville campus (**Manhattanville)** and (b) Columbia University Irving Medical Center (**CUIMC)** (together, the **Columbia Component),** (2) NYSPI (the **NYSPI Component)** and (3) NYPH (the **NYPH Component)**. The Columbia and NYSPI Components are managed in close cooperation with the Columbia Magnetic Resonance Research Center (the **CMRRC).**

This Manual does not cover the use of MR in clinical practice.

B. Basis of Magnetic Resonance

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

Magnetic field is measured in units of Tesla (**T**), which equals 10,000 Gauss (**G**).

C. MR Hardware

MR units consist of three primary systems, each with potential safety risks: the superconducting magnet, the gradient systems and the radiofrequency coils.

Superconducting Magnet

The MR superconducting magnet is essentially a large coil of superconducting wire wound around the axis of the bore. and immersed in a cryogenic fluid such as liquid helium to maintain

superconductivity at very low temperatures (i.e., 4 Kelvin (**K**)). When an electric current is applied to this wire, a magnetic field is produced. The main magnetic field strengths in research range from 1.0 T to 9.4 T. The magnetic field strength must be uniform across the imaging field of view. These fields are approximately 10,000-100,000 times the earth's surface magnetic field. The current required to produce such a field is on the order of hundreds of amperes. As a result, the majority of MR magnets use superconducting wire immersed in liquid helium.

The U.S. Food and Drug Administration (**FDA)** guidelines refer to a magnetic field of 5 G (0.0005 T) as the upper limit where the field strength is of no potential concern for the general public. A line called the "5-G line" (the **5-G Line**) is often drawn around the magnet to show this limit.

Gradient Systems

MR units make use of applied magnetic field gradients to spatially encode the MR signal in three dimensions. Gradient coils are subject to rapidly changing currents, which are necessary to provide spatial encoding within the time constraints of pulse sequences. Gradient systems can carry electrical currents of hundreds of amperes. The coils require dedicated cooling systems to remove the heat induced by the changing currents. The rapid switching of the gradient coils can also cause very loud noise levels of up to 120 decibels (**dB)**.

Radiofrequency Coils

MR units require **transmission coils** to excite nuclear magnetization inside a person's body for imaging and **receive coils** to acquire the nuclear MR signal after transmission. Coils of different sizes and shapes are available to accommodate different anatomic areas. RF coils are sensitive to unintentional background electronic noise; as a result, MR unit rooms are encased in a metallic shield to block all external electromagnetic signals that might fall within the operating frequency.

D. Risks Associated with MR

The following is a brief summary of the most common risks associated with MR. Protective measures against these risks are described in more detail in later sections.

Missile Effect

The missile 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 and speed. When this occurs, the missile effect can pose a significant risk to anyone in the path of the projectile, and can also cause significant damage to the scanner.

To guard against accidents from metallic projectiles, the 5-Gauss 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 before entering the magnet room. All personnel must be trained and certified before given access to the magnet room.

All equipment to be taken into the scanner room, including housekeeping supplies, research equipment, tools and emergency equipment must be made of nonferrous material and labeled MR Safe (as defined in Section II(D) below).

Rotational and Translational Forces

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

Implants and devices that are not MR Safe may pose a serious health risk due to torque and heating. Implants and devices that are MR Conditional (as defined in Section II(D) below) may pose serious health risks if exposed beyond their listed conditions. For instance, implants tested at 1.5 T are not necessarily safe at 3 T. All implants and devices must be documented as MR Safe or MR Conditional before being permitted in the MR Environment (as defined in Section II(C) below).

To prevent damage or injury due to torsion or translational forces, all individuals who enter the magnet room must be screened to determine if they have any ferrous material on or in their body. See Section VI below for further information on screening.

Radiofrequency Fields

Conducting materials within the RF field of a scanner may result in a concentration of electrical currents sufficient to cause excessive heating and tissue damage. Absorption of RF power by tissue is quantified in terms of Specific Absorption Rate **(SAR)** that is expressed in watts/Kilograms (**W/kg).** The FDA has established limits on the SAR relative to the part of the body being scanned and the length of time of the scan.

The local power deposited in a tissue is proportional to the tissue conductivity and the square of the local electric field produced by the RF transmission system. As field strengths increase, estimating and managing the SAR limit is crucial for subject safety. SAR estimation requires knowledge of the electric field at each point inside the subject's body, together with knowledge of local tissue conductivity, both of which are variable.

The main risk of RF fields is burns. Skin contact against RF transmission and receive coils and cables can result in direct burns. Coils and cables are typically insulated and sealed within a thick plastic protective sleeve to provide a minimum safe distance. Clothing or nonconductive pads can provide protection.

More common are burns from electromagnetic induction, where generated current from changing magnetic fields produces an excessive amount of heat. Gradient or RF coils provide the source of the fluctuating magnetic fields, but the current can be produced within any conducting material, either internal or external to the body. The MR Research Safety Program has policies and procedures designed to reduce the risk of burns, as described in Section VII(D) below.

Acoustic Noise

Rapid movement of the gradient coils on non-conducting substrates due to rapid switching of the gradient magnetic field is the main source of acoustic noise within the scanner room. Acoustic noise levels during scanning generally fall between 65 and 95 dB**,** but can reach more than 120 dB. Acoustic noise levels vary depending on the pulse sequence, field strength and other factors. Hearing protection may lower these exposures by about 20 dB, but this may vary according to the type of protection being used.

Participants in MR studies are required to wear ear plugs and/or headphones to reduce the noise. See Section VII(C) below.

Peripheral Neurostimulation

Induced electrical currents can produce uncomfortable or painful neurostimulation in subjects, typically in the arms and legs where the gradient magnetic field is changing most rapidly. The risk of peripheral neurostimulation is dictated by the rate of change of the gradient magnetic field over time, termed *dB/dt,* and expressed in Tesla per second. The FDA requires that dB/dt be set to levels at or below the median threshold for peripheral neurostimulation. Sensitivity to peripheral neurostimulation varies widely among individuals. The induction of cardiac arrhythmia is also possible from the gradient magnetic field changes, but at dB/dt levels far greater than those causing peripheral neurostimulation.

Cryogenic Liquids

The coils of the superconducting magnet are immersed in liquid helium to maintain superconductivity and prevent excessive heat buildup. due to high current. Under normal operation, the helium slowly boils off and more liquid helium must be added periodically. Risks associated with liquid helium include burns due to accidental direct contact with the cryogen or hypoxia as a result of a leak or quench.

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

II. FACILITIES, EQUIPMENT AND SECURITY

A. Locations and Scanners

There are currently multiple locations used for MR research at the Program Institutions:

Manhattanville

The MR facility at Manhattanville (the **ZMBBI MR Facility**) is located in the SC basement of the Jerome L. Greene Science Center (the **Greene Building)** and houses two Siemens 3T MR Systems and a Bruker 9.4T Animal System. Scanning is performed only for research at this location.

CUIMC

The MR facility at CUIMC (the **NI MR Facility)** is located in the Neurological Institute and houses four 3T GE Premier MRI systems. There is also a 3T GE Premier system at the ColumbiaDoctors facility at 51 West 51st Street (the **CD MR Facility** and, together with the NI MR Facility, the **CUIMC MR Facilities).** Both clinical and research scanning are conducted at these Facilities.

NYSPI

The MR facility at NYSPI (the **NYSPI MR Facility**) is located in the Herbert Pardes Building and houses two 3T GE Premier body scanners. Scanning is performed only for research at this location.

NYPH

NYPH uses a number of MR scanners, principally for clinical diagnosis, but also in clinical research. The scanners are located throughout the NYPH facilities, including the Herbert Irving Pavillion, Milstein Hospital Building, Morgan Stanley Children's Hospital, Presbyterian Hospital Building, the Allen Pavilion and Lawrence Hospital **(the NYPH MR Facilities**).

The ZMBBI MR Facility, the CUIMC MR Facilities, the NYSPI MR Facility and the NYPH MR Facilities are referred singly as a **MR Facility** and collectively to as the **MR Facilities.**

All scanners at the Program Institutions intended for and capable of use on humans are FDA-approved.

B. Zones and Signage

Each MR Facility is conceptually divided into four zones, as follows:

Zone I: This includes all areas that are freely accessible to the general public and through which MR Personnel (as defined in Section C below), research subjects and other visitors access a MR Facility.

Zone II: This includes the area between Zone I and Zone III that has limited access, but poses no magnetic field threat. Typically, research subjects are greeted and screened in Zone II. Subjects are not free to move throughout Zone II at will, but must be under the supervision of MR Personnel.

Zone III: This includes the area in which there may be a risk of serious injury or death from the MR scanner. All access to Zone III is strictly restricted. The boundaries of the 5 Gauss Line within Zone III should be clearly and visibly marked (e.g., with a red line on the floor and signs indicating the presence of the magnetic and electrical fields). Access authorization is required for Zone III and Non-MR Personnel (as defined in Section C below) are prohibited from entering the Zone. Specifically identified MR Personnel are charged with ensuring that this guideline is strictly adhered to.

Zone IV: This area is the scanner room itself, where all access is strictly restricted. Zone IV should be demarcated and clearly marked as being potentially hazardous.

Annex A to this Manual contains a map of each of the locations where MR research is conducted, with the Zones and the 5-G line indicated on each map.

As used in this Manual, the **MR Environment** includes that portion of a MR Facility in which access is controlled and the magnetic field may pose a risk, or, in other words, Zones II, III and IV.

All of the MR Facilities are required to have clear signage posted in each Zone that indicates the hazards present and access restrictions. **Annex B** to this Manual illustrates the signage that is used in all of the MR Facilities.

C. Security and Access

Unauthorized access to any of the MR Facilities 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 magnet bore. As a result, access to any MR Facility is restricted.

Access to each of the MR Facilities is controlled by either electronic swipe card access or manual key access.

The personnel levels outlined below define access and scanning privileges for the MR Facilities. Personnel who wish to work in any MR Facility must meet the eligibility and training requirements (as described in Section IV) for their level of access.

Non-MR Personnel: Any person who is not trained or certified with respect to the MR Facilities as a Level 1 or 2 MR Personnel, including janitorial and cleaning staff, any Facilities and Public Safety personnel and emergency responders. Non-MR Personnel are prohibited from entering any part of the MR Facility other than Zone I unaccompanied.

Level 1 MR Personnel: At this level, personnel are permitted access to Zones II, III and IV unaccompanied, but are prohibited from escorting any Non-MR Personnel into Zone IV. If qualified, Level 1 MR Personnel may include staff members or any other workers required for supporting roles in the control or magnet rooms. NYSPI does not designate personnel as "Level 1 Personnel".

Level 2 MR Personnel: At this level, personnel are permitted unsupervised access to all Zones and may accompany human subjects or research animals in such rooms. At NYSPI, Level 2 Personnel are identified by a green badge. Individuals who have not been fully approved for a green badge may be given a yellow badge, which permits them access to the control room, but not to Zone IV.

MR Operators: At this level, personnel are permitted unsupervised access to the scanners in Zone IV and may scan phantoms, animal, and/or human research subjects as approved. Approval for one type of subject does not necessarily mean approval for other types of subjects. MR Operators must also be trained and approved as Level 2 Personnel. In some locations these individuals may be referred to as "Level 3 MR Personnel."

The individuals who are Level 1 MR Personnel or Level 2 MR Personnel are referred to in this Manual as **MR Personnel.**

D. Equipment and Labeling

All equipment, instruments and devices should be clearly labeled to indicate their safety status in the MR Environment. There are typically three types of safety indications: **MR Safe, MR Conditional** and **MR Unsafe**.

MR Safe: an item that poses no known hazards in the MR Environment. MR safe can only be applied to objects that are 100% safe to be taken, used or placed within the MR Environment without any risk of potential harm. MR Safe items include non-conducting, non-metallic and non-magnetic items.

MR Conditional: an item that has been demonstrated to pose no known hazards in a specified MR Environment with specified conditions of use. Field conditions that define the specific MR Environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), RF fields and SAR. For MR Conditional items, the item labeling will include results of testing sufficient to characterize the behavior of the item in the MR Environment. In particular, testing for items that may be placed in the MR Environment should address magnetically induced displacement force and torque and RF heating. Other possible safety issues include thermal injury, induced currents/voltages, electromagnetic compatibility, neurostimulation, acoustic noise, interaction among devices, the safe functioning of the item and

the safe operation of the MR system. An item with this label warns the user that there are limitations to the usability or to the testing that was performed on it. In other words, the item may have been tested for a 1.5 T system, but not for a 3 T system. Any parameter that affects the safety of the item should be listed and any condition that is known to produce an unsafe condition must be described on the item, in its packaging or in its accompanying instructions.

MR Conditional items should not be stored in the MR Environment, and should be brought into the MR Environment only by Level 2 Personnel who are cognizant of the operating conditions and can confirm that such items' restrictions are compatible with those conditions.

MR Unsafe: an object that poses a known threat or hazard in the MR Environment. MR Unsafe items are **prohibited** from Zones III and IV.

All equipment in the MR Facilities must be labeled for suitability for the MR Environment. Unmarked objects should be assumed to be MR Unsafe unless they are clearly non-metallic throughout. MR Unsafe items include magnetic materials.

E. Non-Emergent Engineering and Equipment Servicing and Repair Work

The scanners and other equipment in a MR Facility must be checked and, if necessary, repaired on a regular non-emergent schedule. In advance of any work done, the applicable MR Research Director will contact the appropriate faculty and staff and the vendor to evaluate the impact of the work on the scanners and MR operations. Thereafter, the staff of the MR Facility will work with the engineer to schedule the work.

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III. ROLES AND RESPONSIBILITIES

It is the responsibility of all faculty, staff, students and visitors at the Program Institutions to conduct MR activities in the safest possible manner so as to not adversely impact themselves, institutional property or the surrounding community. The following are brief descriptions of the principal players in the MR Research Safety Program.

Please note that these descriptions only relate to personnel involved in MR research safety and do not include, for instance, those personnel who manage or oversee the activities of the CMRRC or who are involved only in clinical MR use.

A. Joint MR Research Safety Committee

The Joint MR Research Safety Committee **(JMRSC)** has been established under the MR Research Safety Program to be responsible for safety matters in the MR Facilities. The JMRSC is comprised of individuals from each of the Program Institutions who are knowledgeable about MR equipment, MR experimental procedures, MR research and the physics involved in MR scanning of human beings and animals. The members and Chair are appointed jointly by the Executive Vice President for Research of the University, the Executive Vice President and Dean of the Faculties of Health Sciences and Medicine of the University, the President and Chief Executive Officer of NYPH, and the Director of NYSPI, or in each case a designee.

The JMRSC will perform, at a minimum, the following safety-related tasks:

- Review the MR safety policies and this Manual periodically and revise the same as needed;
- Convene as needed, but no less than once per year;
- Approve the use of implants and devices (a) that are unlabeled, (b) that are labeled MR Conditional, but are subject to novel or non-standard scanning conditions that fall outside of the strict conditions listed for the implant or device or (c) as to which there is current uncertainty as to their safety (**Uncertain MR Devices)**;
- Review reports of MR Research Safety Issues (as defined in Section XI(A)) on a quarterly basis or as needed; and
- In the event that a MR Research Safety Issue occurs, oversee the implementation of a corrective and preventive action plan if needed.

The JMRSC and Subcommittees referred to below will be governed by and operate pursuant to written By-Laws.

B. Protocol Review Subcommittee

The Protocol Review Subcommittee (**PR Subcommittee**) is a subcommittee of the JMRSC that is responsible for the review of (1) protocols for certain studies involving human subjects as described in Section V(A) (**Human Subjects MR Research Studies)** and (2) protocols for

certain studies involving animals as described in Section IX(B) **(Animal MR Research Studies)** (collectively, **PRS Research Studies).**

PRS Research Studies requiring review may not receive Institutional Review Board (**IRB**) or Institutional Animal Care and Use Committee (**IACUC**) approval until PR Subcommittee approval has been granted. References to the "IRB" in this Manual mean either the University IRBs or the NYSPI IRB, as appropriate.

The PR Subcommittee is comprised of representatives of each Program Institution, and must include at least (1) a MR Safety Officer, (2) a MR physicist, (3) a radiologist, (4) a veterinarian, (5) a human subjects researcher using MR, and (6) an animal subjects researcher using MR. The members and Chair of the PR Subcommittee shall be appointed by the Chair of the JMRSC. The Chair of the PR Subcommittee shall be a rotating position, serving for a term established by the By-Laws of the JMRSC.

C. Device and Implant Safety Subcommittee

The Device and Implant Safety Subcommittee (**DIS Subcommittee)** is responsible for the review of issues referred to it by the JMRSC or the MR Safety Officers.

In particular, the DIS Subcommittee reviews issues relating to Uncertain MR Devices when there is disagreement between the JMRSC and any MR Research Safety Officer or among the members of the JMRSC as to their MR compatibility. The Subcommittee makes recommendations to the JMRSC, which may make the final determination regarding implants and devices that may be used in the scanner at issue.

The DIS Subcommittee is comprised of the MR Safety Officers and the MR physicists from each site.

D. MR Research Directors

There are three MR Research Directors at the Program Institutions, one for each of the CUIMC/NYPH Component, the NYSPI Component and the ZMBBI Component. Each MR Research Director has overall responsibility for the Facilities within their Component and all MR operations at such Facilities. Each MR Research Director will perform, at a minimum, the following safety-related tasks at the applicable MR Research Facility:

- Oversee the conduct of MR research at such Facility;
- Maintain current knowledge of the MR research protocols involving such Facility and assist investigators in setting up new protocols;
- Work with the other MR Research Directors, and oversee development of appropriate training materials to be used in all MR Research Facilities; and
- Supervise the implementation of the MR Research Safety Program's policies and procedures (the **MR Research Policies and Procedures)**.

Facilities engaging in clinical research have designated a MR Medical Director (**MRMD**) as the individual who is ultimately responsible for MRI use in clinical care. In these cases, the MRMD may fulfil the functions of the MR Research Director.

E. MR Safety Officers

Each MR Research Facility has a designated MR Safety Officer, who is experienced and knowledgeable about the operation of MR scanners, the safety hazards relating to MR scanning and the MR Research Safety Policies and Procedures. Each MR Safety Officer will perform, at a minimum, the following safety-related tasks relating to the applicable MR Facility:

- Ensure that the MR Safety Policies and Procedures are followed during the execution of approved MR research protocols;
- Advise the other MR Safety Officers and the JMRSC about needed changes in the MR Safety Policies and Procedures;
- Work with the other MR Safety Officers to prepare and update as necessary all MR Research safety training materials and conduct in-person training;
- Verify that any personnel involved in such Facility has the requisite training for his/her role;
- Maintain documentation and records for safety and compliance, training, participant screening, quality assurance and incidental findings within such Facility and take such actions as are necessary to correct any MR Research Safety Issue;
- Work with the other MR Safety Officers and the DIS Subcommittee in determining the safety of devices and implants;
- Suspend any activity in such Facility that in his/her judgment violates the MR Research Safety Policies and Procedures or that otherwise constitutes an unsafe condition;
- Report MR Research Safety Issues in accordance with Section XI(B);
- Respond to incidents and emergencies as needed during and after normal work hours; and
- Remain current on all regulatory and other policies and recommendations regarding MR research safety.

F. MR Research Operators

Each MR Research Facility has one or more operators (**MR Research Operators)**, each of whom is trained and approved (as noted in Section IV(A) below), who works directly with users and study participants to perform structural and functional scans. They are responsible for operating the scanners in such Facility; together with members of a research team, screening participants prior to scanning; preparing participants for scans; providing immediate medical treatment and assistance when necessary; responding to incidents and accidents within such Facility and processing and maintaining MR data. Each MR Research Operator will perform, at a minimum, the following safety-related tasks relating to the applicable MR Facility:

- Restrict access to such Facility to authorized individuals and participants;

- Conduct safety screening for research participants and individuals accompanying participants;
- Respond to incidents, accidents or emergencies within such Facility;
- Oversee routine cleaning and maintenance of such Facility;
- Monitor and maintain temperature and other requirements for the scanner, including water and helium levels;
- Operate each MR scanner in such Facility to include routine and experimental setups, modify scanning parameters to optimize data, perform daily quality assurance testing and perform basic troubleshooting of scanner malfunction;
- Greet and interview research participants, document screening interviews, prepare subjects for scanning, converse with subjects during scanning, remove subjects from the scanner after scanning and conduct follow-up interviews with participants;
- Support users of the scanner with paradigm implementation and other needed assistance; and
- Maintain accurate and appropriate records of the use of the scanner and of participant studies.

G. Principal Investigators

The Program Institutions' policies provide that principal investigators (**PIs)** are responsible for overseeing all research projects for which they act as PI. Each PI will perform, at a minimum, the following safety-related tasks at the applicable MR Research Facility:

- Follow all MRI Research Safety Policies and Procedures;
- Require that all projects for which they are responsible comply with relevant regulations, policies and procedures for MR use in human subjects or animals;
- Obtain the appropriate approvals from the IRB or IACUC;
- Conduct research studies in compliance with IRB or IACUC protocols;
- Require that all MR Research Operators involved in their research maintain training requirements and follow all relevant policies and procedures;
- Communicate instances of accidents and unsafe work conditions to the applicable MR Research Director;
- Comply with the incidental findings policies of the applicable Program Institution; and
- Inform research personnel and research participants of potential hazards associated with MR research.

H. MR Physicists

Each MR Research Facility shall have the necessary physicists on staff to oversee the technical aspects of the magnet, including upgrades and installation of software or hardware; serve as a point of contact with the applicable manufacturer of the scanner; and coordinate with the applicable MR Research Director regarding the development of quality assurance testing to meet the needs of the MR Research Operators.

IV. TRAINING

MR Personnel receive training in MR safety and operations commensurate with their role and the duties they perform. It is the responsibility of each person to obtain the necessary training and to maintain proper training certification. The training is the same for all of the Program Institutions, except to the extent differences are required by the configuration of the particular MR Research Facility or the type of MR equipment. The training at each MR Research Facility is overseen by the applicable MR Safety Officer.

A. MR Personnel Training

The following constitute the training requirements for Level 1 and Level 2 MR Personnel, and MR Operators:

Level 1 MR Training:

- Successfully complete the Level 1 MR Safety Training course and pass the Level 1 MR Safety test;
- Undergo a safety screening and be approved by the applicable MR Research Director for safe entry into the MR Environment;
- Review this Manual; and
- Complete annual refresher training thereafter.

Level 2 MR Training:

- Meet all the requirements for Level 1 MR Personnel certification;
- Successfully complete the Level 2 MR Safety Training course and pass the Level 2 MR Safety test; and
- Complete annual refresher training thereafter;

MR Operator Training: Level 2 Personnel may be approved as MR Operators to perform scans on phantoms, animals, and/or human subjects. Approval for one type of subject does not permit scanning of other types of subjects.

- Meet all the requirements for Level 2 MR Personnel certification;
- Successfully complete the MR Operator (may be called Level 3 MR) Safety Training course, or obtain equivalent experience from experienced lab members as approved by the applicable MR Research Director;
- Demonstrate independent operation of experimental procedures under the direct supversion of approved MR Operators;
- Pass the MR Operator (may be called Level 3 MR) certification test; and
- Complete annual refresher training thereafter.

In place of the training requirements above, individuals who are currently certified in MR by the American Registry of Radiologic Technologyists (ARRT) or the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT), or licensed radiologic technologists in the State

of New York must complete only the safety screening and review of this Manual noted above to be considered MR Operators for all scan types.

MR Operator personnel qualifications are reviewed annually by the applicable MR Research Safety Officer.

B. Training for Non-MR Personel

Training in MR Safety Awareness and orientation to MR Research Facilities will be offered as needed to individuals either working in the vicinity of MR scanners or with responsibility to respond to incidents in or around MR scanners. This training will include the recognition of warning signs and access controls, the hazards associated with MR equipment, and how to avoid risk of injury in MR Research Facilities.

V. REVIEW OF HUMAN SUBJECTS MR RESEARCH PROTOCOLS

A. General Requirements

Scanning of human subjects for a research study is not permitted without the prior approval of the IRB, and, when required, the PR Subcommittee.

B. Studies Requiring PR Subcommittee Review

Research studies involving any of the following factors are required to be submitted to the PR Subcommittee for review:

- Operation of new or custom (i.e., non-FDA approved) imaging equipment (e.g., coils, receivers, etc.);
- Use of non-manufacturer-provided pulse sequences that exceed the scanner "Normal Mode" or, for scanning of healthy subjects, the scanner "1st Level Control Mode"; or
- Enrollment of healthy pregnant or minor subjects.

C. Review of Proposed Human Subjects MR Research Applications

For Columbia Studies:

An Application with respect to a proposed Human Subjects MR Research Study, together with the related Hazardous Materials Appendix R (**Appendix R)**, must be submitted to the PR Subcommittee via Rascal.

For NYSPI Studies:

A Protocol Summary Form with respect to a proposed Human Subjects MR Research Study, together with the related Appendix R, must be submitted to the PR Subcommitte via Rascal.

In either case, the research protocol and the informed consent form with language describing the potential risks from MR scanning will be reviewed by the PR Subcommittee.

The required information in Appendix R includes:

- Location of scanning and equipment to be used
- Use of non-FDA approved imaging equipment in the scan, if applicable
- Use of non-manufacturer-provided pulse sequences that exceed the scanner "Normal Mode" or, for scanning of healthy subjects, the scanner "1st Level Control Mode", if applicable
- Names of the MR Operator and other personncel performing scans
- Use of equipment or materials from outside the applicable MRI Facility in the scanner room during scanning procedures

- Use of contrast, sedation or other medication, if applicable
- Scan time per session and number of sessions per subject
- Justification for the use of healthy preganant or minor subjects, if applicable.

From the above data, the PR Subcommittee shall evaluate the following:

- Anticipated maximum temperature rise under expected conditions
- Potential for peripheral nerve stimulation
- Interference with normal safety precautions (i.e., hearing protection)
- Other anticipated risks to research subjects
- Appropriateness of informed consent.

MR Physicsts may assist with the above evaluations.

D. Non-clinical, Non-research Scanning Protocols

Under limited circumstances, MR scans may be performed for purposes that are not clinically indicated, but also fall outside of the strict definition of research. The use of phantoms is encouraged whenever possible, but there may be circumstances when phantoms cannot adequately mimic the physiological processes that affect a MR scan. Examples of such circumstances include:

- Protocol development or refinement to ensure adequate image quality
- Training and teaching of MR Research Operators
- Quality assurance (**QA)** testing (when appropriate QA phantoms are not available)

One or more "umbrella" research protocols may be developed and reviewed by the IRB to address these types of procedures. All proposals for non-clinical, non-research studies must be submitted to the PR Subcommittee for review and approval.

Scanning for non-clinical, non-research studies may be performed only on healthy adult volunteers. Any individuals from vulnerable populations, and/or those who are impaired and unable to provide informed consent are excluded. All volunteers must undergo regular screening procedures, and complete an informed consent form that is equivalent to that provided for human subjects research.

VI. SAFETY SCREENING

All individuals, including operators, researchers, staff, students, research participants and visitors, must be screened prior to entering a MR Research Facility. This is an extremely important procedure because of the risks that the MR magnet can pose and should be executed with the utmost care.

The following sections describe the screening processes and the concerns relating to certain devices and implants.

A. Screening of Research Subjects, Companions, Visitors, Researchers, Staff, and Students

All individuals who are not approved MR Personnel must pass the following screening process prior to entering Zone III. Any person who is not a research subject, but who will accompany a subject into Zone III, must be screened in the same manner as the subject.

B. Telephone Screening of Research Subjects and Additional Screening Prior to Arrival at the MR Research Facility

At least two weeks before a scheduled scan date, at the time a research participant is contacted by research personnel to set up an appointment for scanning, the participant should be screened for pacemakers, metallic implants, ocular implants and other relevant considerations at the time the participant is contacted by research personnel to set up an appointment for scanning. Participants who will receive contrast agent should be screened for renal disease.

All research subjects who may have devices, implants or other internal ferromagnetic objects must be contacted by telephone by Level 2 Personnel to establish additional methods of screening. Examples of such methods include subject history, plain x-ray films, prior CT or MR studies of the relevant anatomic area or access to written documentation as to the type of device, implant or foreign object that might be present. Once positive identification has been made as to the type of device, implant or foreign object, best effort assessments should be made to identify the MR compatibility of the device, implant or object. A prior MR scan is not sufficient to clear a subject for an MR scan without verifying the device or implant.

Any questionable devices, implants or foreign bodies should be discussed with approved MR Operators at the applicable MR Research Facility. Compatibility with the particular scanner and scan protocol should be confirmed. If there are any uncertainties as to whether to approve the scanning, the procedures described in Sections D and/or F below should be followed.

C. Completion of Screening Form

Upon the arrival of **any** Non-MR Personnel, including any person accompanying a research subject, at the applicable MR Research Facility, their identity will be checked by MR Personnel and recorded. If the subject lacks capacity, a legally authorized representative of the subject may

act on his/her behalf. If so, the accompanying adult must present proof of his/her status as a legally authorized representative at the same time that the research subject's identity is checked.

After the individual is identified, they must complete a MR Safety Screening Form (the **MR Screening Form).** MR Screening Forms should be made available in both English and Spanish and if necessary, a translator should assist in communication with the subject. For research subjects, this Form must be completed each and every time the subject undergoes scanning. A family member or a legally authorized representative of a subject who cannot reliably provide his/her own medical history should also complete the Form. A template of the MR Screening Form is attached to this Manual as **Annex C.**

The MR Screening Form shall be orally reviewed with the individual by Level 2 MR Personnel and discussed with the subject, family member or legally authorized representative to ensure that the questions are understood and answered correctly.

The completed MR Screening Form shall be reviewed and approved only by a MR Research Operator. If there are any uncertainties as to whether to approve the scanning, the procedure described in Section F below should be followed. The Form should also be signed by the individual (or their legally authorized representative).

Any person with a contraindication accompanying a research subject will only be allowed into Zone II and should be instructed to wait in that area for the subject's scanning to be completed.

Completed MR Screening forms will be maintained on file for a minimum of the number of years that documentation with respect to the applicable research study is required to be maintained

D. Ferromagnetic Personal Belongings and Ferromagnetic Scanning

Following completion and sign off of the MR Screening Form, the research subject should be asked to remove the following objects, if any:

- Belts
- Bobby pins and hair clips
- Cell phones
- Clothing with metallic threads and/or embellishments (most zippers and rivets are acceptable)
- Colored contact lenses
- Credit cards
- Dentures, partial plates and nonpermanent retainers (dental fillings and standard crowns are acceptable)
- Glasses
- Hearing Aids
- Insulin pumps (unless the pump is known to be MR Safe or Conditionally Safe; however, the outer battery pack must be removed in all cases)
- Jewelry, including facial/body piercings

- Keys
- Loose change
- Medication/birth control/pain patches with foil backings; the subject's physician should decide whether the patch can be removed
- Prosthetics
- Temporary metallic tattoos
- Underwire bras
- Wallets
- Watches

It is recommended that subjects leave their street clothes and shoes in a locker in Zone II and dress in Facility-supplied gowns and booties prior to entering the scanning area. Areas of the body that will be subject to RF energy during the scan may be gowned, with exceptions for convenience or comfort so long as any items listed above are removed.

The entire body surface of each subject should then be scanned with a handheld ferromagnetic screening wand. The wand should be passed slowly and carefully over the subject, nearly making contact. The wand should be used only after all of the other screening procedures have been completed and not as a substitute for them.

If there are any doubts regarding the metal screening responses, do not allow the individual to enter Zone III. The fact that the individual has been scanned previously is never a sufficient basis upon which to conclude that the subject can enter Zone III safely, since a person's physical status may have changed since the last scan and risks may vary according to the magnetic field strength of the particular MR equipment to be used.

E. Pregnant Research Subjects and Personnel

The MR Screening Form includes questions relating to pregnancy. MR scanning has no known risks to a pregnant female or the fetus, but it is prudent to know if a female is pregnant so that she can make an informed decision as to whether or not to be scanned. Pregnant females are eligible for scanning when explicitly included in the approved IRB protocol.

A urine pregnancy test should be provided to any female of child-bearing age upon request. A female who indicates on the MR Screening Form that she does not believe that she is pregnant may be scanned after the Form is reviewed by the appropriate MR Personnel. If the subject is unsure whether she could be pregnant, a urine test should be offered. If the subject knows that she is pregnant or has a positive urine pregnancy test, her participation in the research study must be discussed with the MR Safety Officer. More stringent pregnancy testing requirements and participation limitations may be specified in the approved IRB protocol, and if so, must be followed.

Any other individuals (companions, visitors, or staff, including MR Personnel) who are or may be pregnant may not remain in the MR scanner room while the RF and gradients are operating. Pregnant individuals may remain in the control room and enter the magnet room between scans, during the study.

F. Engineers and Other Service Providers

Engineers and other service providers who need access to the MR Environment must go through the regular screening process described in Section A above.

If an engineer or other service provider plans to work in the magnet room, all tools will be carefully screened prior to entry into the room as follows:

- All MR Safe tools are safe to use in the magnet room.
- All MR Conditional tools must be checked to make sure that all specified conditions are met.
- Tools that are neither MR Safe or MR Conditional may not in any circumstances be brought into the magnet room.
- Any tools that are not properly labeled will be evaluated outside the magnet room by Level 2 MR Personnel with metal detectors or other appropriate screening equipment.

G. Contraindications for MR Scanning

As indicated in Section II(D) above, devices are divided into the categories "MR Safe", "MR Conditional" and "MR Unsafe". As a general rule, any metallic or (active) electronic medical device has the potential to cause harm within a MR Environment. As there are many devices and implants on the market with particular characteristics, it is beyond the scope of this Manual to describe all of them and their compatibility with the Program Institutions' MR equipment.

If there are any doubts regarding whether an individual may be safely scanned, do not allow the individual to enter the scanner room. Information regarding the safety of a subject's device or implant may be obtained from many sources, including the subject and/or their family, a device identification card and the electronic medical record, including prior imaging (although previous MR scanning should not be the sole evidence of MR safety of an implant or device). A vast database that categorizes MR imaging safety ratings and recommendations for nearly all known medical devices is available at https://www.mrisafety.com This website is frequently updated and a hard copy reference, which additionally covers the American College of Radiology (**ACR**), the American Society for Testing and Materials (**ASTM)** International and FDA guidelines, is also available. In addition, many manufacturers also publish MR imaging safety information and guidelines for their devices on their websites. In some cases, the lot and model numbers of a device are necessary to determine its degree of MR imaging compatibility. A note from the subject's surgeon may be required.

This guidance may be used to assess contraindications for research subjects. If there are remaining questions regarding whether a research subject is permitted to be scanned, it should be addressed in accordance with the process described in Section F below:

- **Implants and Medical Devices**
  These will be evaluated on a case by case basis following the recommendations of the involved physicians and the guidance of MRISafety.com.

- **Post-operative conditions**

These will be evaluated on a case by case basis following the recommendations of the involved physicians and the guidance of MRISafety.com.

- **Past eye injuries**

Participants with a history of foreign bodies in the eyes will require a negative CT scan of the orbits prior to being admitted to Zone III or IV.

- **Tattoos**

Tattoos are not an absolute contraindication for MR procedures. However, heavily tattooed individuals, particularly of the head and neck should be instructed to be alert for any heating sensations and to notify the magnet operator (by using the squeeze ball) should they experience any discomfort. Participants with tattoos may or may not be eligible for MR scanning based on the opinion of the magnet operator or the researcher.

For participants with extensive or dark tattoos, including tattooed eyeliner, to decrease the potential for RF heating of the tattooed tissue, it is recommended that cold compresses or ice packs be placed on the tattooed areas and kept in place throughout the MR scanning if these tattoos are within the volume in which the body coil is being used for RF transmission. This approach, described in ACR Guidance on MR Safe Practices 2013, is especially appropriate if fast spin echo (or other high RF duty cycle) MR sequences are anticipated in the study. If local transmit coil, Q-Body or multichannel transmit coil (e.g. in 7T systems) is being used for RF transmission, a decision must be made if high RF transmitted power is to be anticipated by the study protocol design. If so, then the above precautions should be followed. Additionally, participants with tattoos that were placed within 48 hours before the pending MR scanning should be advised of the potential for smearing or smudging of the edges of the freshly placed tattoo.

- **Skin staples and Superficial Metallic Sutures**

Participants who have skin staples or superficial metallic sutures **(SMS)** may be permitted to undergo MR scanning if the skin staples or SMS are not ferromagnetic and are not in or near the anatomic volume of RF power deposition for the study to be performed. If the nonferromagnetic skin staples or SMS are within the volume to be RF irradiated for the requested MR study, several precautions are recommended:

  - Warn the participant and make sure that he/she is particularly aware of the possibility that he/she may experience warmth or even burning along the skin staple or SMS distribution. The participant should be instructed to report immediately if he/she experiences warmth or burning sensations during the study (and not, for example, wait until the end of the knocking noise).
  - It is recommended that a cold compress or ice pack be placed along the skin staples or SMS if this can be safely clinically accomplished during the MR scanning. This will help to serve as a heat sink for any focal power deposition that may occur, thus decreasing the likelihood of a clinically significant thermal injury or burn to adjacent tissue.

- **Drug delivery patches**

Some drug delivery patches contain metallic foil. Scanning the region of the metallic foil may result in thermal injury. Because removal or repositioning can result in altering of patient dose, consultation with the PI of the study or the subject's physician is indicated in assessing how to best manage the subject. If the metallic foil of the patch delivery system is positioned on the subject so that it is in the volume of excitation of the transmitting RF coil, the case should be specifically reviewed with a radiologist, the PI or the subject's physician. Alternative options may include placing an ice pack directly on the patch. This solution may still substantially alter the rate of delivery or absorption of the medication to the subject (and be less comfortable to the subject, as well). This ramification should therefore not be treated lightly, and a decision to proceed in this manner should be made by a knowledgeable radiologist and with the concurrence of the subject's physician as well. If the patch is removed, a specific staff member should be given responsibility for ensuring that it is replaced or repositioned at the conclusion of the MR scan.

- **Aneurysm clips**

Any research subject with a cranial aneurysm clip will require a written report from his/her physician stating the name of the clip and the date of placement prior to being admitted to Zone III or IV. Only subjects with MR Safe or MR Conditional aneurysm clips are allowed to undergo MR scanning.

H. Unanticipated Ferromagnetic Implant

It is possible that during the course of MR scanning, an unanticipated ferromagnetic implant or foreign body is discovered within a research subject undergoing the scanning. In such cases, it is imperative that the applicable MR Safety Officer be immediately notified of the suspected findings. This MR Safety Officer should then assess the situation, review the imaging information obtained and decide what the best course of action might be. There are numerous potentially acceptable courses that might be recommended that are in turn dependent upon many factors, including the status of the subject, the location of the suspected ferromagnetic implant/foreign body relative to the local anatomic structures, the mass of the implant, etc. Appropriate courses of action might include proceeding with the scan under way, immobilizing the subject and his/her immediate removal from the scanner or other intermediate steps. Regardless of the course of action selected, it is important to note that the forces on the implant will change, and may actually increase, during the attempt to remove the subject from the scanner bore. It is thus prudent to ensure that the subject be immobilized and extracted in a slow, cautious and deliberate rate.

I. Procedure for Resolving MR Safety Questions

Whenever possible, contraindications and safety questions should be resolved before the subject arrives at the MR Facility. If there is any question at the completion of the screening immediately prior to scanning, the subject may only enter the scanner with the explicit permission of the MR Safety Officer for the applicable MR Research Facility.

When a possible contraindication (see Section D above) is identified during the initial screening, the following steps must be taken:

- The person completing the screening will refer the individual's case to the MR Safety Officer. The MR Safety Officer may request that additional information with respect to the reason for the contraindication (e.g., implant make and model number) be collected.
- If the MR Safety Officer can make a confident decision (positive or negative) using the subject's information and https://www.mrisafety.com or other resources, the decision will be communicated to the study PI.
- If not, the MR Safety Officer should communicate to the study PI that there is a possible contraindication, and ask for confirmation from the PI to pursue scanning of the subject.
- If the PI confirms the request to scan the subject, the scan and subject information should be referred to the DIS Subcommittee.
- The DIS Subcommittee will consider the case and may make a consensus decision regarding the approval to scan the subject.
- If the Subcommittee cannot reach consensus, or if the Subcommittee makes a negative determination and the PI chooses to appeal the decision of the Subcommittee, the case will be referred to the JMRSC.

VII. OTHER PROCEDURES RELATING TO SCANNING OF HUMAN SUBJECTS

A. Review by MR Safety Officer

Prior to scheduling any scanning for any Human Subjects MR Research Study, the PI of such study shall send to the applicable MR Safety Officer the following documents:

- Approved Appendix R
- Evidence of IRB approval of protocol and informed consent form.

B. The Magnet Room

Proper ambient conditions, including temperature ($\leq$ 22°C or 72°) and humidity ($\leq$60%), should be maintained in the magnet room. Deviation from these standards should be reported to the applicable MR Safety Officer immediately.

All equipment and instruments required for scanning will be readied and in place prior to the subject being brought into the magnet room.

All items that are not already present in the scanner room must be approved by the MR Safety Officer.

C. Preparing the Subject

Subjects may have completed the Informed Consent process well in advance of the scan being performed. Prior to performing the scan, subjects should be reminded of MR side effects such as claustrophobia, dizziness, warming, twitching muscles, tingling sensation, etc. In addition, for all MR Research Facilities other than those at NYPH, it should be made clear to the subject that emergency medical services may not be available on site. Following such discussion, the subject shall be given the opportunity to withdraw consent and decline to be scanned.

Participants should be given padding to ensure comfortable positioning during the scan, as well as a blanket, should they want one.

As it is important to assure the participant that he/she will be visible to and in hearing contact of the MR Research Operator at all times. All participants will be given an “alert bulb” to hold during the scan session, which can be squeezed to alert the scanning Operators that the subject wishes to talk to them or to be removed from the scanner. The subject should be instructed to notify the MR Research Operator of any discomfort at the first hint. See Section IX below for procedures to follow in a medical emergency.

D. Acoustic Noise Protection

All subjects must use earplugs or acoustically shielded headphones during scanning.

E. Protection Against Thermogenic Risks

Precaution should be taken to prevent local thermogenic pain, damage or systemic stress during the scanning as follows:

- Avoid skin-to-skin contact; the subject's hands should not be placed on his/her hips and the subject's arms should not be crossed. The subject should be instructed to refrain from allowing their legs, feet, hands, arms, etc. to cross or overlap during the scanning. A spacer should be placed between the feet so that the toes and calves are not touching when restricting movement of legs for pelvic imaging.
- Use padding to separate a subject's limbs and body from the magnet bore, and his/her legs from his/her torso. There should be no body loops formed through adjacent tissue contact with arms or legs.
- Route cables in a straight line. Do not coil cables or allow them to touch the subject.
- Ensure that no body part is in direct contact with the bore. A minimum distance (typically 5 mm, but dependent upon specific scanner model) is required between the bore and the subject.
- Cold packs should be available for application to areas of concern to prevent heating.
- Use the lowest possible SAR values in the scanning.
- Maintain two-way communication between the MR operator and the subject throughout the scanning.

F. Infection Control

In order to prevent communication of disease to other subjects or personnel, the following steps should be followed:

- Operators should wash hands between all subjects.
- The sheets or other coverings on the MR table should be changed after each subject.
- All contaminated items will be discarded in red bags marked for regulated medical waste
- The sharps container will be removed if ¾ full
- The magnet room table and headrest will be wiped with a Sani-wipe at the end of each day
- Any bodily fluids must be cleaned using standard infection control procedures. Any contaminated surfaces will be cleaned and treated with an appropriate disinfectant.

VIII. SCANNING WITH CONTRAST AGENTS

The use of gadolinium-based contrast agents (**GBCAs)** in MR imaging is well established and some research protocols require such contrast agents. GBCAs are well tolerated by a majority of subjects and their safety profile is excellent. The most serious risks are anaphylactoid reactions and nephrogenic systemic fibrosis. The ACR has issued guidelines which can be found in the ACR Manual on Contrast Media: Version 9 on the ACR website http://www.acr.org/~/media/ACR/Documetns/PDF/QualitySafety/Resources/ContrastManual/2013_Contrast_media.pdf

In accordance with the ACR Guidelines, no research subject should be administered prescription MR contrast agents without orders from a duly licensed physician. Licensed Radiologic Technologists who been certified for contrast injection may start and attend to peripheral IV access lines. Contrast certified MR Technologists may administer FDA-approved gadolinium-based MR contrast agents by means of peripheral IV routes as a bolus or slow or continuous injection as directed by the orders of a duly licensed physician.

The name of the administered contrast agent, the administered dose and route (and rate, if applicable) of administration, as well as any adverse reactions should be recorded for all contrast agents administered.

The use of gadolinium-based contrast agents carries the risk of side effect such as allergic reactions to the contrast agent. See https://www.fda/drugs/postmarekt-drug-safety-information-patients-and-providers/information-gadolinium-based-contrast-agents for more information.

In the event of an adverse reaction to contrast, immediately remove the subject from the MR Environment. If reaction is mild (limited itchy skin or throat, transient flushing or warmth, minor nausea or headache, etc.), you may monitor the subject until symptoms subside. If the reaction is more serious or the symptoms do not subside, call 911 (or activate emergency response team if at NYSPI or NYPH).

IX. REVIEW OF ANIMAL MR RESEARCH PROTOCOLS

A. General Requirements

Scanning of animals for a research study is not permitted without the prior approval of (1) the IACUC, (2) Environmental Health and Safety (**EH&S)** and (3) the PR Subcommittee, if required. Studies that are considered low risk (based on the type of scan, length of the scan, equipment used and/or ancillary procedures involved) may be approved administratively by EH&S without full PR Subcommittee review.

B. Studies Requiring PR Subcommittee Review

Only those research studies using full-size MR equipment will be required to be submitted to the PR Subcommittee for review; studies involving only small-bore MR equipment inaccessible to large animals are not required to be reviewed.

C. Review of Proposed Animal MR Research Applications

For Columbia Studies:

A Protocol with respect to a proposed Animal MR Research Study, together with a Hazardous Materials Appendix S (**Appendix S)**, must be submitted to the PR Subcommittee via Rascal.

For NYSPI Studies

A Rascal Abbreviated Protocol form and the attached NYSPI protocol, together with the related Appendix S, must be submitted to the PR Subcommittee via Rascal.

The information required in an Appendix S includes:

- Location of scanning and MR equipment to be used
- Species to be scanned
- Equipment or materials from outside of the applicable MR Facility to be used
- Names of the MR Research Operator and other personnel involved in the scanning
- Use of anesthesia, contrast, sedation, other medication, or hazardous or infectious agents, as part of the scanning procedures
- Imaging sequences to be used, area of body to be scanned and positioning of animal for scanning
- Anticipated duration of scans, number of scans per animal and number of animals.

From the above data, the PR Subcommittee should evaluate the following:

- Anticipaed maximum temperature under expected conditions
- Interference with normal safety precautions
- Other antipated risks to the subjects.

The PR Subcommittee may impose additional constraints on or requirements with respect to the scanning procedures as a condition to its approval of the study.

X. PROCEDURES RELATING TO SCANNING OF ANIMAL SUBJECTS

A. Personnel

Laboratory Personnel participating in animal scanning must be approved as Level 2 Personnel or accompanied by, or under the immediate supervision of and in visual or verbal contact with, at least one Level 2 MR Personnel for the entirety of their duration within Zone III or Zone IV. They must go through the normal screening procedures outlined in Section VI prior to being permitted entry into Zone III.

Laboratory Personnel performing scans in animals must be approved MR Research Operators. If not, they must arrange in advance to have an approved MR Research Operator present to run their scan.

There must be at least two individuals in the control room at all times during the scanning, one of which must be an approved MR Research Operator. In any case, one of the two individuals must be qualified by the Institute of Comparative Medicine (**ICM**) to accompany animals in the MR Research Facility. If the ICM-qualified individual is an approved MR Research Operator, the second person need only be Level 2-certified.

Only ICM veterinary staff and members of the research staff who are certified as qualified by the ICM (**Qualified Research Staff)** are allowed to accompany animals in the MR Research Facility.

MR Research Personnel must ensure that no unqualified Non-MR Personnel enter the magnet rooms.

B. Personal Protective Equipment (PPE)

PPE must be worn by all persons in a room where animals are located. All persons having contact with non-human primates must wear a minimum of a head bonnet, face mask, face shield/goggles, double layer nitrile/latex gloves and disposable gown/lab coat.

C. Equipment

The following parties will have responsibility for providing and maintaining the equipment and supplies listed under their name. All equipment and supplies in the MR Research Facility must be properly labeled to indicate that they are to be used only for animal scanning.

ICM Veterinary Staff
The ICM maintains an inventory of mateirals and equipment that may be used during MR scanning that is supplied to the MR Research Facility staff. If the list is updated or any materials are added, the new information should be supplied to the MR Research Facility ahead of the planned scanning.

- PPE
- MR compatible anesthesia machine with ventilator
- Medications/drugs relating to anesthesia or veterinary care
- Consumable medical supplies
- Animal "crash box"

MR Research Facility

- Vital sign monitors designated "Animal Use Only"
- Surface disinfectant

PI

- Contrast agents, if needed

D. Requirements Prior to Scanning

The patient table any other areas in the magnet rooms that may have direct contact with the research animals must be cleaned and sanitized by ICM veterinary staff or Qualified Research Staff with hospital grade disinfectant to prevent disease transfer to the research animals. Disinfectant will be provided by the MR Facility.

Whenever possible, surfaces will be covered by absorbent pads to minimize contact between the research animals or any animal body fluids and the MR devices.

ICM veterinary staff or Qualified Research Staff will be responsible for placing the animal onto the MR table and attaching the animal to vital sign monitors and an anesthesia machine.

The MR Operator must review the setup of the animal for safety prior to initiating scanning.

E. Requirements During the Scanning

ICM veterinary staff or Qualified Research Staff will be responsible for monitoring animal vital signs during scans.

If possible, ICM veterinary staff will make adjustments to anesthesia or vital sign monitors between scans to allow scans to run without interruption.

When necessary, ICM veterinary staff or Qualified Research Staff may instruct the MR technician or investigator to stop the scan to assess the animal's vital signs, make adjustments to vital sign monitors or conduct medical interventions. MR Research Personnel will follow such instructions.

F. Requirements Following Scanning

All surfaces that had direct contact with research animals must be sanitized with hospital grade disinfectant by the ICM veterinary staff or Qualified Research Staff to prevent disease transfer to humans. Disinfectant will be provided by the MR Research Facility.

All materials that had direct contact with research animals must be disposed of as biohazardous waste.

A scheduling gap may be required between animal and human scans to allow for any odors associated with animals to dissipate.

The ICM will monitor the animal for a period of at least seven days following scanning to check for any injuries or other adverse events. Any findings will be reported immediately to the appropriate MR Safety Officer.

XI. EMERGENCY PROCEDURES

The following sections describe the procedures that must be followed in the event of an emergency. Please follow the instructions for the particular MR Facility in which the emergency occurs.

A. Medical Emergencies

In the event of a subject medical emergency, the following actions must be taken:

1. Stay calm and, if possible, instruct the subject to remain calm.

2. Stop the scan immediately.

3. Evaluate the subject to establish the status of the emergency.

4. **IF YOU ARE AT THE GREENE BUILDING:**
   Call 911 and the Manhattanville Department of Public Safety emergency number 212-853-3333 (on campus 3-3333) immediately from the nearest phone. Provide your name, call back number, exact location and information about the nature and magnitude of the medical emergency. Public Safety will be responsible for coordinating the arrival of the first responders to the scene.

   IF YOU ARE AT CUIMC:
   Call 911

   IF YOU ARE AT NYSPI:
   Call x5555 and relay the location and nature of the emergency to the response team. If the case of a psychiatric emergency, state that it is one. The NYSPI Safety Director will announce a psychiatric emergency over the PA system, asking all available personnel to respond to the location.

   IF YOU ARE AT NYPH:
   Follow the procedures described in Section IV.4 of the NewYork-Presbyterian Hospital Policy and Procedures Manual-R113_Magnetic Resonance Imaging (MRI) Safety (the NYPH MR Safety Manual).
   https://infonet.nyp.org/QA/HospitalManual/R113MagneticResonanceImaging.pdf

   A copy of the NYPH MR Safety Manual is also attached hereto as **Annex D.**

5. Free the subject from the coils and all immobilization devices.

6. Emergency procedures should not be administered in the magnet room and no medical equipment is allowed in the magnet room other than plastic restraints. Instead, a MR Research Operator will assist with the removal of the subject immediately from the magnet room via a MR

compatible transport stretcher and relocated to an area where the emergency will be handled by the medical response team. The magnet room door will be closed upon removal of the subject to avoid entry of any metallic objects.

7. If emergency resuscitation is required, any appropriately trained and certified personnel should immediately initiate basic life support (airway, breathing, chest compression) until the arrival of the emergency personnel.

IF YOU ARE AT NYSPI: Security officers will bring the crash cart from the NYSPI security desk.

8. Level 2 MR Personnel must coordinate with Public Safety or emergency responder personnel on the scene to ensure that no such personnel enter Zone III or Zone IV without proper screening. Such personnel must be informed of the MR Environment risks if they have to enter Zone III or Zone IV and they may enter only when deemed safe by MR Personnel.

9. Call the applicable MR Safety Officer, MR Research Director, the PI (if not already onsite) and the emergency medical contact listed in the IRB protocol or consent form. The applicable IRB should be notified in writing within 24 hours of the emergency.

10. An incident report should be completed.

B. Ferrous Object Emergency

In the event that a ferrous object or MR Conditional device is pulled up to or into the magnet, the following actions should be taken:

1. If any person is pinned by a ferrous object or a MR Conditional device in the scanner and is considered to be in a harmful or life-threatening situation, a MR Personnel will press the Emergency QUENCH button to quench the magnet. See Section E below for quenching procedures.

2. If a ferrous object or MR Conditional device is pulled up or into the magnet and there is no immediate danger to the subject or any employee, a quench is NOT needed.

3. MR Personnel will remove the subject from the scan room and close the magnet room door.

4. Call the applicable MR Safety Officer, MR Research Director, the PI (if not already onsite) and the emergency medical contact listed in the IRB protocol or consent form (if the subject has been injured).

5. An incident report should be completed.

C. Fire Emergency

In the event of a fire when a subject is in the bore, the following actions should be taken:

1. Stay calm and instruct the subject to remain calm.

2. Stop the scan immediately.

3. **Press the EMERGENCY POWER OFF button. Close all doors.**

4. Free the subject from the coils and all immobilization devices.

5. Move the subject from the magnet room as rapidly and safely as possible.

6. **IF YOU ARE AT THE GREENE BUILDING:**
   Once you are safely out of the fire region, **call 911 and the Manhattanville campus emergency number (212) 854-3333 (on campus 3-3333)** from the nearest phone. Provide your name, call back number, exact location and information about the nature and magnitude of the fire. Public Safety will be responsible for coordinating the arrival or the first responders to the scene.

   IF YOU ARE AT NYSPI:
   Call X5555 and identify the type and location of the fire.

   IF YOU ARE AT CUIMC:
   Call 911

   IF YOU ARE AT NYPH:
   Follow the procedures described in Section VII of the NYPH MR Safety Manual.
   https://infonet.nyp.org/QA/HospitalManual/R113MagneticResonanceImaging.pdf

7. If the fire is small, MR Operators and appropriately trained Level 2 MR Personnel may use a MR Safe or MR Conditional fire extinguisher stored in Zone III or Zone IV to **control and extinguish the fire.** Do this only after emergency personnel have been called, evacuation has started and Public Safety has been notified (if applicable). If the fire cannot be controlled with one fire extinguisher, it is deemed to be out of control.

8. MR Operators or Level 2 MR Personnel must coordinate with on the scene emergency personnel to ensure that no Fire Department personnel enter Zone III or Zone IV without proper screening. The Fire Department personnel must be informed of the MR environmental risks if they have to enter Zone III or Zone IV.

9. Call the applicable MR Safety Officer and MR Research Director to inform him/her of the fire.

10. If the fire is out of control and Fire Personnel have to enter Zone III or Zone IV with their equipment, the MR Technologist must **initiate a quench** (see Section E below). All Non-MR Personnel should be prohibited from entering Zone III or Zone IV until a MR Operator or Level

2 MR Personnel have verified with a Gauss meter that the static field has decayed to below 5 Gauss.

D. Emergency Off

An **Emergency Off** button is located on the wall of each MR magnet room and on the MR Research Operator's console. It removes all electrical power from the MR console and the patient table, including any power sources from the Uninterrupted Power Supply. The effect of pushing the Emergency Off button is to turn off the entire MR system EXCEPT for the static magnetic field and magnet rundown unit; hence this DOES NOT PRODUCE A QUENCH. The button should be used only to stop a scan during a patient emergency or during a serious equipment fault or hazard, such as fire or water in the vicinity of the MR equipment. Only an experienced MR Research Operator, MR Physicist, MR Safety Officer or MR Research Director of the particular MR Facility is permitted to use the Emergency OFF button if this type of emergency should occur.

E. MR Magnet Quench Procedures

A **Quench** occurs when a superconducting magnet suddenly loses its field. During a quench, the magnetic current dissipates as heat, causing the liquid helium to boil off in gaseous form. MR installations are designed with ventilation systems to handle the rapid coil off of liquid helium appearing as white clouds of vapor. These vapors can push oxygen out of the magnet room.

Typically, almost all of the helium will escape safety through the quench pipes to the outside air, and the quench presents no serious danger. If there is a blockage or failure of the venting system, the helium may accumulate in the magnet room, which is an **emergency situation.** Helium itself is colorless, odorless and tasteless. Helium vapor is extremely cold and causes water condensation that look like steam. Prolonged exposure to helium vapor can result in asphyxiation, frostbite or other injuries.

There is an oxygen sensor in the magnet room that will detect any rapid change in the oxygen content of the room and alert staff members inside and outside of the room of a potential problem. Impending magnet quenches are heralded by a loud noise, a warning message on the MR Console or the tilting of the image on the screen of the console.

A quench can occur spontaneously or intentionally.

An **Intentional Quench** should be initiated **ONLY** in two situations: (a) when a subject is pinned by a ferromagnetic object and is in a life-threatening situation or (b) when there is a fire in the magnet room that is out of control and Fire Department personnel need to enter the magnet room with their own equipment, such as air tanks and axes.

In the event of an **Intentional Quench with Pinned Subject in the Magnet in a Life-threatening situation, with Functional Quench Pipes,** the following actions should be taken:

1. Stay calm and instruct the subject to stay calm

2. Stop the scan immediately.

3. **Press the Magnet STOP button to start the quench procedure.**

4. **Press the EMERGENCY POWER OFF button to shut down the power supply.**

5. The magnet room exhaust fan should be turned on and the magnet room door propped open to promote air circulation. If the door cannot be opened because of pressure from the cryogen in the room, the window to the magnet room should be broken using a plastic hammer to relieve pressure, thereby allowing the MR Research Operator to gain entry into the room and assist the subject.

6. Transport the subject out of the room. Evacuate as much of the area as possible.

7. **IF YOU ARE AT THE GREENE BUILDING:**
   Call 911 and the Manhattanville Public Safety campus emergency number (212) 854-3333 (on campus 3-3333). Provide your name, call back number, exact location and information about the nature of the emergency. Public Safety will be responsible for coordinating the arrival of the emergency response personnel to the scene.

   IF YOU ARE AT CUIMC:
   Call 911

   IF YOU ARE AT NYSPI:
   Call x5555 and relay the location and inform the emergency response team that a magnet quench has occurred.

   IF YOU ARE AT NYPH:
   Follow the procedures described in Section VII of the NYPH MR Safety Manual.
   https://infonet.nyp.org/QA/HospitalManual/R113MagneticResonanceImaging.pdf

8. MR Operators or Level 2 MR Personnel must coordinate with on the scene Public Safety personnel to ensure that no emergency responders enter Zone III or Zone IV until Level 2 Personnel have verified with a Gauss meter that the magnetic field has decayed to below 5 Gauss.

9. Call the applicable MR Safety Officer and MR Research Director.

10. Do not touch the magnet; restrict magnet access by all MR Personnel.

In the event of an **Intentional Quench due to an Uncontrolled Fire in the Magnet Room; with Functional Quench Pipes,** the following actions must be taken:

1. Stay calm and instruct the subject to remain calm.

2. Stop the scan immediately

3. Free the subject from the coils and all immobilization devices.

4. Remove the subject from the magnet room **immediately. Evacuate the fire region as quickly as possible.**

5. **Press** the Magnet **STOP button** to start the quench procedures.

6. **Press the EMERGENCY POWER OFF button** to shut down the power supply.

7. **IF YOU ARE AT THE GREENE BUILDING:**
   Call 911 and the Manhattanville Public Safety campus emergency number (212) 854-3333 (on campus 3-3333). Provide your name, call back number, exact location and information about the nature of the emergency. Public Safety will be responsible for coordinating the arrival of the emergency response personnel to the scene.

   IF YOU ARE AT CUIMC:
   Call 911

   IF YOU ARE AT NYSPI:
   Call x5555 and relay the location and inform the emergency response team that a magnet quench has occurred.

   IF YOU ARE AT NYPH:
   Follow the procedures described in Section VII of the NYPH MR Safety Manual.
   https://infonet.nyp.org/QA/HospitalManual/R113MagneticResonanceImaging.pdf

8. MR Operators or Level 2 MR Personnel must coordinate with on the scene Public Safety personnel to ensure that no Fire Department personnel enter Zone III or Zone IV until a MR Operator or Level 2 MR Personnel have verified with a Gauss meter that the magnetic field has decayed to below 5 Gauss.

9. Call the applicable MR Safety Officer and MR Research Director.

10. Do not touch the magnet; restrict magnet access by all MR Personnel; wait for service engineers to arrive.

In the event of a **Spontaneous Quench; No Subject Emergency, with Functional Quench Pipes,** the following actions must be taken:

1. Stay calm and instruct the subject to remain calm.

2. **Stop the scan immediately.**

3. Free the subject from the coils and all immobilization devices.

4. Move the subject from the magnet room **immediately.**

5. **IF YOU ARE AT THE GREENE BUILDING:**
   Call 911 and the Manhattanville Public Safety campus emergency number (212) 854-3333 (on campus 3-3333). Provide your name, call back number, exact location and information about the nature of the emergency. Public Safety will be responsible for coordinating the arrival of the emergency response personnel to the scene.

   IF YOU ARE AT CUIMC:
   Call 911

   IF YOU ARE AT NYSPI:
   Call x5555 and relay the location and inform the emergency response team that a magnet quench has occurred.

   IF YOU ARE AT NYPH:
   Follow the procedures described in Section VII of the NYPH MR Safety Manual.
   https://infonet.nyp.org/QA/HospitalManual/R113MagneticResonanceImaging.pdf

6. Call the applicable MR Safety Officer and MR Research Director.

7. Do not touch the magnet; restrict magnet access by all MR Personnel; wait for the service engineers to arrive.

XII. REPORTING

The following describes the requirements for the continuous evaluation of the principal indicators of subject safety to ensure safe research practices in the MR Research Facilities.

A. Research Safety Log

The applicable MR Safety Officer will maintain a log (the **Research Safety Log)** in which the following items **(MR Safety Issues)** will be recorded:

- Non-conformance with or deviations from MR Safety Policies and Procedures
- Non-conformance with or deviations from conditions of an approved Appendix R, Appendix S, or other scanning procedures specified by the MRSO
- Subject Adverse Events (as defined in Section D below)
- Subject complaints
- Near Miss (as defined in Section D below) events

In addition, the Research Safety Log should include any items the applicable MR Safety Officer identifies pertaining to regulatory issues or recommendations for changes in the MR Safety Policies and Procedures.

Any MR Personnel should notify the applicable MR Safety Officer if they believes that a MR Safety Issue has occurred.

B. MR Safety Officer Reporting Requirements

The applicable MR Safety Officer must report the following:

- To the applicable MR Research Director, in a timely manner, any MR Safety Issue and, if required, the proposed corrective and preventive action plan relating to such Issue.
- To the JMRSC, quarterly, a report on all MR Safety Issues occurring in such quarter and the implementation of any corrective and preventive action plans.
- To the PI of a research study, promptly but no later than two days following the occurrence of a MR Safety Issue relating to the PI's study, a description of such Issue and the proposed corrective and preventive action plan relating to such Issue. It is the PI's responsibility to determine whether the MR Safety Issue constitutes a protocol violation or an unanticipated problem that must be reported to the IRB or IACUC.
- To the manufacturer of the MR equipment, within 10 business days following the occurrence of a MDR Reportable Event (as defined in Section D below), the information required in FDA Form 3500A.
- To the FDA, within 10 business days following the occurrence of a MDR Reportable Event that has resulted in the death of a research subject, a completed FDA Form 3500A.
- If any MDR Reportable Event has occurred in any year, to the FDA on July 1 of such year (for MDR Reportable Events occurring in January-June of such year) or January 1 of

the following year (for MDR Reportable Events occurring in July-December of such year), a completed FDA Form 2419.

C. MR Research Operator and/or Technologist Reporting Requirements

The MR Research Operator or Technologist must report to the MR Safety Officer any incident noted in Section A above. In addition they must also report the following:

- To the applicable MR Research Director immediately by telephone the occurrence of any subject medical emergency or fire emergency
- To the subject's electronic medical record, an incident report following any emergency involving the subject (where applicable)
- A Clarity event to the applicable department for incidients at CUIMC
- An NYPH KEEPSAFE report for incidents involving patients and/or staff of NYP
- An accient report to Columbia University Human Resources and EH&S for any injury to Columbia staff

D. Definitions

For purposes of this Manual, capitalized terms are defined as follows:

- **Adverse Event:** any untoward or unfavorable incident, experience or outcome relating to the MR equipment or any MR procedure in any MR Research Facility that results in physical or psychological injury to a human or animal research subject or otherwise increases the risk to subjects or others in any research study involving MR procedures.
- **MDR Reportable Event:** the death of or serious injury to a human research subject or other person caused by an incident involving the MR equipment in any MR Research Facility or to which such MR equipment may have contributed because of (a) a failure or malfunction of such equipment, (b) the improper or inadequate design of such equipment, (c) the manufacture of such equipment, (d) the labeling of such equipment or (e) an error by a user of such equipment.
- **Near Miss:** an incident that did not result in injury to a research participant or other person, but had the potential to do so.

ANNEXES

Annex A – Maps of locations in the MR Research Facilities where MR research is conducted, including Zones and 5-G lines

Annex B – Sample Signage used in the MR Research Facilities

Annex C – MR Screening Form Template

Annex D – NYPH MR Safety Manual