Standard Operating Procedure
DISC Human Subject Safety SOP
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Department of Radiology

Diagnostic Imaging Sciences Center (DISC)
MR Research Laboratory - AA048-HSC

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1. Introduction

This Standard Operating Procedure (SOP) provides operational guidelines for the Diagnostic Imaging Sciences Center (DISC). DISC operations are expected to meet or exceed state, federal, and international regulatory and good research guidelines for ensuring Magnetic Resonance Imaging (MR) safety. It is subject to inspection by regulatory authorities and is, therefore, a controlled document that should be created and maintained in a consistent manner. All DISC staff members are expected to follow approved DISC SOPs.

The MR safety procedures outlined in this document are based on the following Food and Drug Administration recommended guidelines:

- ASTM F2052-00 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment
- ASTM F2119-01 Standard Test Method for Evaluation of MR Image Artifacts From Passive Implants
- IEC 601-2-33 - Medical Electrical Equipment - Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

And on the ACR Guidance Document for Safe MR Practices: AJR 2007; 188:1-27.

And on the following Philips Medical Systems recommended guidelines for MR safety:

- Frank G. Shellock, PhD. e.g. “Reference Manual for Magnetic Resonance Safety, Implants, & Devices”, Biomedical Research Publishing Group, Los Angeles, CA
- MRSAFETY.COM

See References Section (1.6) for more information on these guidelines.

1.1 Purpose

This document provides the safety measures to operate the Magnetic Resonance Imaging (MR) scanner for human studies (3T Philips Achieva) located in the Diagnostic Imaging Sciences Center (DISC). DISC is a School of Medicine (SOM) on-campus research facility (a ‘911’ facility). The DISC MR Research Laboratory will be used only for research and there will be no billing to a third party medical services payor unless otherwise approved.

1.2 Scope

This SOP applies to the 3T Philips MR scanner operated by DISC at AA-048 Health Sciences Center, 1959 NE Pacific, under the Department of Radiology, School of Medicine, University of Washington research operations.

1.3 Deviations

Deviations are not permitted unless approved by the DISC Operations Committee. Reasons for a deviation must be reviewed and approval must *be documented.*

1.4 Personnel and Committees

The following personnel and committees play key roles in DISC operations.

1.4.1 DISC Operations Committee

The DISC Operations Committee consists of a director, a general manager, imaging scientists, licensed

physicians, and MR radiology technologists. (See Appendix 1 for current members.) The Committee is responsible for insuring that DISC MR operations meets or exceeds MR safety regulations. Its duties include:

- Review MR Safety for DISC research projects
- Organize MR Safety Training and Lectures for DISC MR users
- Oversee MR operator training and certify qualified operators
- Monitor and oversee MR operations

1.4.2. DISC Safety Committee

An MR Safety Committee will be appointed by the MR Laboratory Director and approved by the Operations Committee. The Safety Committee will consist of a chair, scientists and technologists experienced in MR operations and safety. The duties of the Safety Committee include:

- Review annually: safety policies and make recommendations for changes or updates to the Director and Operations Committee
- Assist in the design and implementation of curriculum for safety training of Laboratory personnel and users
- Review and approve new equipment for use in the MR environment. This will include insuring it is safe for use and specify any conditions/restrictions to be followed to insure safety of personnel and equipment
- Provide documentation of device approval/non-approval
- Appoint a Safety Officer from among the Committee members

1.4.3. MR Safety Officer

The MR Safety Officer is to serve as the onsite referee for monitoring day-to-day safety in the Laboratory and to answer safety questions that may arise.

1.5 Glossary

- ASTM: originally known as American Society for Testing and Materials, now has developed into one of the largest voluntary standards development organizations in the world.
- RT: MR radiology technologist
- SOM: School of Medicine
- NP: Nurse Practitioner
- EH&S: Environmental Health and Safety
- IRB – Human Subjects Research Review Committee
- 1959 NE Pacific, Health Sciences Center AA-048, University of Washington, Seattle, WA 98195 is the location of the Diagnostic Imaging Sciences Center (DISC) 3T MR

1.6 References

CDRH Draft Document: "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems" http://www.fda.gov/cdrh/ode/primerf6.html

"CDRH Guidance for Testing MR Interaction with Aneurysm Clips, Draft Document" http://www.fda.gov/cdrh/ode/odeclips.html

Copies of the ASTM standards may be purchased from ASTM at http://www.astm.org/

Copies of the ACR Guidance Document for Safe MR Practices 2007: AJR 2007;188:1-27

Copies of the IEC standard may be purchased from ANSI at http://www.ansi.org/

MRSAFETY.COM: http://www.MRsafety.com/

2. MR System Testing: Scientific Instrument Inspection

The Scientific Instrument inspection involves an array of MR system periodic maintenance tests aimed at ensuring that the MR system functions properly. These tests include phantoms, physical observation, radiofrequency shielding verification, cryogen consumption, radiofrequency coils, B_0 field homogeneity, gradient field strength, evaluation of eddy currents, radiofrequency calibration, quality of the radiofrequency output, quadrature phase detection, signal-to-noise ratio, image uniformity, image linearity, slice thickness, stability of the magnetic field image acquisition software, image processing software, and acoustics. The MR system is under Philips Medical Systems warranty or service contract (current contract update expires June 2010) and MR system testing is completed by Philips Medical Systems. Log Books documenting dates of inspection/service, types of service and repair of problems will be kept in the MR Laboratory Control Room.

The University of Washington has inspected, tagged and certified this equipment and will do so annually.

3. Human Subject Safety

Detailed policies regarding safe operation and conduct in the MR Laboratory are contained Addendum 7 in Guidelines for Safe Operation and Conduct in the MR Research Laboratory. The following guidelines will be followed to ensure the safety of human research subjects.

3.1 Human Subject Consent Forms

Research involving human subjects may not be performed without prior written approval by the IRB. If the experiment involves special coils or techniques that the study may be associated with specific risks, these will be clearly stated in the research protocol and consent form, and will be approved by the Human Subject Division of the University of Washington as part of the review process. Potential risks associated with 3T MR imaging will be clearly and consistently stated in a consent form. MR scans will only be performed after research subjects have read, understood and agreed to the study, and signed the consent form.

3.2 Human MR Scanner Operators

Only a certified MR RT or personnel with equivalent or similar qualification recognized by the Operations Committee can conduct human scanning. It is mandatory for the RT to have at least two years experience with MR operations. If an operator candidate does not have a RT certificate, the Operations Committee will review the qualifications of the individual based on the following criteria outlined in Appendix 8 for Training and Certification for MR Operations in Human Subject Scanning:

- Operator has passed all University of Washington required human research subject study courses, including HIPPA and MR safety training classes
- Operator must be CPR and BCLS certified
- DISC Operations Committee has tested and confirmed that the operator has met MR clinical experience requirements as per the American Registry of Radiologic Technologists
  OR
- Operator has conducted human subject MR scans under the supervision of an experienced MR-certified radiology technologist and/or practicing physician. Operator must demonstrate clinical competence in the areas of general patient care activities and MR equipment operation as defined in Appendix 8 in Training and Certification for MR Operations in Human Subjects Scanning.

- Operator has requisite knowledge of all DISC and Philips Medical Systems MR system manuals and SOPs.

3.3 Emergency Squeeze Ball

An emergency squeeze ball will be offered to each human subject before the scanning procedure begins. The emergency ball must be functional and allows subjects to stop the scanning if they deem it necessary.

3.3.1 Thermal Safety

All persons undergoing an MR procedure must wear scrubs or other all cotton, non-conducting clothing into the magnet room. No jeans, zippers or other decorative items are allowed in the magnet.

3.3.2 Acoustic Safety

All persons must wear sound protection to minimize the risk of hearing injury. Ear plus or acoustic headphones are standard available devices unless alternative ear protection devices are approved.

3.4 Monitoring of Subjects

Human subjects will be monitored visually and verbally throughout the procedure by the MR Operator.

3.5 Human Subject Screening

The establishment of thorough and effective screening procedures for human subjects is one of the most critical components of MR research activities. These screening procedures are the same as those used at the University of Washington Medical Center (UWMC) to guard the safety of all those preparing to undergo MR procedures or to enter the MR room. An important aspect of protecting human subjects from MR system-related accidents and injuries involves an understanding of the risks associated with the various implants such as: pacemaker, devices aneurysm clip, cochlear implant and other objects that may cause problems in this setting. We will constantly update information and documentation about new medical implants in order to provide the safest possible MR setting.

3.5.1 Human Subject Screening Form

The MR Safety Screening Form (Appendix 2) is used to acquire basic information from a subject. This form will be filled out by the subject and reviewed by the MR Operator prior to their entry into Zone 3 in the controlled magnet area.

All research subjects must fill out and sign the MR screening safety form. This MR Safety Screening Form is first reviewed by all recruiters and study coordinators during the recruiting process of the projects. The recruiters and coordinators will be trained by certified MR operators in basic MR screening procedures such as presenting questions to avoid ambiguous answers. If human subjects can not recall if they have had prior surgery with implants or injury of any kind that may involve metal, these subjects will be excluded from MR scans.

At the time of the MR scan, the MR Safety Screening Form will be reviewed by certified MR operators. Further oral interrogation will assure the MR safety screening form is complete and correct before human subjects are escorted into Zone 3. If, after screening the subject, questions remain regarding safety that can be answered through specialized screening procedures such as x-ray examination prior to the MR exam, this may be done at the discretion of the MR operator in consultation with the MR Research Medical Director or designee. If x-ray screening needs to be performed, this screening protocol must be discussed and approved by the IRB.

In rare cases when a final adjudication is needed, the Principal Investigator of the project is required to consult with MR safety experts at the UWMC (Dr. Swati Rane Levendovszky – Director of DISC, PhD, Tim Wilbur – Lead Technologist and Safety Officer of DISC, Michael Hoff – Associate Professor of Diagnostic Physics, Mussie Tesfaldet – Imaging Technologist Supervisor, UWMC).

3.6 Individual Safety Standards

During the project review process, the DISC Operations Committee will tailor its MR safety procedures for the specific medical needs of its individual human subjects. For instance, additional safety procedures may be requested and defined for pediatric subjects who require sedation in the MR to undergo their imaging study.

3.7 Human Subject Medical Emergencies

In case of medical emergency MR operators or investigators will call 911 prior to seeking assistance from licensed physicians in the building. MR operators who are BCLS certified will initiate appropriate life support procedures while waiting for emergency services to arrive.

3.7.1 AED and Crash Cart

A Medtronic Lifepak 500 automated external defibrillator (AED) and a crash cart will be placed in the MR operator's area. The crash cart is a Banyon Emergency Stat Kit 900. The crash cart will be checked daily by the DISC MR Program Coordinator. Backup for this daily check will be provided by the Laboratory Manager. The Oharmaceutical Checklist, Cart Lock Log and Quality Assurance checklist follow as **Appendices 3-5**.

3.8 Scanner Related Emergencies

Magnet related emergencies include emergency stops, magnet emergency, and emergency quench. These are listed in Appendix 6.

3.9 Infection Control

3.9.1 Surfaces

All surfaces including the floor that may come in contact with animal equipment or the animal itself must be covered in plastic or chucks (disposable material). Chucks are taped to the table (to avoid being moved) and placed on the floor when animal equipment is placed on the floor.

3.9.2 Labels

All animal coils and other devices for animal imaging must be labeled "For animal use only." Those devices must be stored in a separate enclosure and completely sealed with plastic. If human coils are used for animal imaging the coils must be covered in plastic as well. Plastic cover should be removed at the end of the procedure and the coil, scanner and laboratory is then cleaned per the DISC Animal SOP.

3.9.3 Work Area

Equipment brought into a DISC work area by an animal research team is assumed to be contaminated. This equipment is placed in a designated work area. No human use space such as console, control area etc can be used to place such equipment.

3.9.4 Handling

Personnel handling the animals are required to have an annual health screening by Environmental Health and

Safety (EH&S) occupational health. Each person who comes in contact with the animals must wear gloves. Hands must be washed with appropriate disinfectant after gloves are removed. Gloves must be removed prior to touching any commonly use items such as doorknobs, keyboards or telephones.

3.9.5 Disposable Materials

All disposable materials are to be placed in biohazard bags and disposed of in the appropriate disposal containers. Lab coats are placed in the red biohazard laundry bin. All other washable materials (towels, sheets, etc.) are handled as universal precaution laundry in yellow bags.

3.9.6 Disinfection Procedures

After animal imaging, all used equipment (i.e., MR coil, magnet bore) and working surfaces (tabletops) must be sprayed with appropriate disinfectant (Clidox-S) and wiped off with paper towel. Floor should be mopped at the end of the day.

Before each human subject MR scan, MR operators will provide a clean sheet, blanket, and cover for the human subject. After each scan, these will be put in the laundry bag and replaced by a new set of linen for the next human subject.

Laboratory personnel handling subjects/patients will wash hands after completion of each subject/patient interaction.

3.10 Incident Reports

MR Laboratory Incident Reports will follow the University of Washington protocols for reporting and filing incident report. The standard, UW 0266 Incident Report form, will be used and distributed accordingly.

The DISC Operations Committee will also review all incident reports.

4. Coverage of drug injection

A Washington state licensed physician or nurse practitioner will monitor contrast agent (or tracer) injection during a study and for a minimum of 20 minutes after contrast agent (or tracer) injection. The need for continued monitoring beyond 20 minutes will be assessed by the DISC Operations Committee based on project review prior to approval of the study. It is the responsibility of the PI of a research project to arrange an MD or NP to be on site whenever a drug injection (including a contrast agent or tracer) is to be done for that project.

5. Revision History

January 14, 2008: Operations Committee Member Update

Appendix 1

OPERATIONS COMMITTEE

(New members are still being sought)

Swati Rane Levendovszky, Director, Diagnostic Imaging Sciences Center
Thomas J. Grabowski, Director, Integrated Brain Imaging Center, Department of Radiology, Neurology
Dushyant Sahani, Professor and Chair, Department of Radiology
Paul Kinahan, Professor and Vice Chair of Research, Department of Radiology, Bioengineering
Mahmud Mossa Basha, Associated Professor andVice Chair of Clinical Operations, Medical Director of MRI, Department of Radiology
Justin Deese, Director of Finance and Administration, Department of Radiology
Jurgen Unutzer, Professor and Chair, Psychiatry and Behavioral Sciences

MRI PROCEDURE SCREENING FORM

Date _____
Name _____
Sex _____ Age _____ Physician _____ Patient No. _____
Date of Birth _____ Height _____ Weight _____
Procedure _____ ❑ Outpatient ❑ Inpatient
Diagnosis _____
Clinical History _____
_____
_____

	YES	NO
Have you ever had a surgical procedure or operation of any kind?	❑	❑
If yes, please list all prior surgeries and approximate dates: _____		
Have you ever been injured by any metallic foreign body? (e.g., bullet, BB, shrapnel, etc.)	❑	❑
Please describe: _____		
Have you ever had an injury to the eye involving a metallic object? (e.g., metal slivers, shavings, foreign body, etc.)	❑	❑
Please describe: _____		
Do you have anemia or diseases that affect your blood?	❑	❑
Do you have a history of renal disease, seizures, asthma, or allergic respiratory disease?	❑	❑
Do you have any drug allergies?	❑	❑
If yes, please list: _____		
Have you ever had a reaction to a contrast medium used for MRI or CT?	❑	❑
Are you pregnant or do you suspect that you are pregnant?	❑	❑
Are you breastfeeding?	❑	❑
Last menstrual period: _____ Post-menopausal?	❑	❑
Are you taking oral contraceptives or receiving hormone treatment?	❑	❑

PERTINENT PREVIOUS STUDIES:

BODY PART	**DATE**
X-rays	_____
Computed tomography	_____
Ultrasound	_____
Nuclear Medicine	_____
MRI	_____

We strongly recommend using the ear plugs or headphones we supply for your MRI examination since some patients may find the noise levels unacceptable and the noise levels may temporarily affect your hearing.

Appendix 2 (cont.)

THE FOLLOWING ITEMS MAY BE HAZARDOUS OR MAY INTERFERE WITH THE MRI EXAMINATION BY PRODUCING AN ARTIFACT.

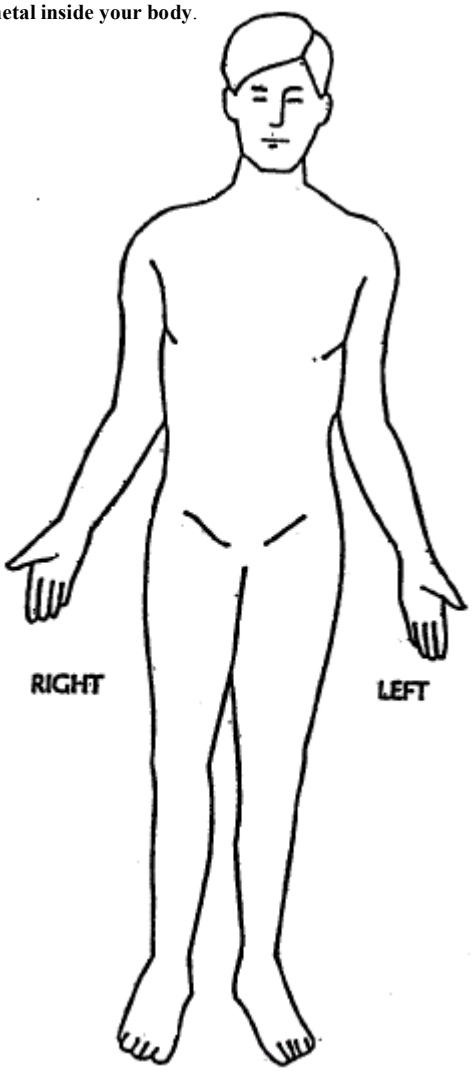
PLEASE INDICATE IF YOU HAVE THE FOLLOWING:

YES NO

- ❑ ❑ Cardiac pacemaker
- ❑ ❑ Aneurysm clip(s)
- ❑ ❑ Implanted cardiac defibrillator
- ❑ ❑ Neurostimulator
- ❑ ❑ Any type of biostimulator
  Type: _____
- ❑ ❑ Any type of internal electrode(s), including
  - Pacing wires
  - Cochlear implant

  Other: _____
- ❑ ❑ Implanted insulin pump
- ❑ ❑ Swan-Ganz catheter
- ❑ ❑ Halo vest or metallic cervical fixation device
- ❑ ❑ Any type of electronic, mechanical, or magnetic implant
  Type: _____
- ❑ ❑ Hearing aid
- ❑ ❑ Any type of intravascular coil, filter, or stent
  (e.g., Gianturcocoil, Gunther IVC filter, Palmaz stent, etc.)
- ❑ ❑ Implanted drug infusion device
- ❑ ❑ Any type of foreign body, shrapnel, or bullet
- ❑ ❑ Heart valve prosthesis
- ❑ ❑ Any type of ear implant
- ❑ ❑ Penile prosthesis
- ❑ ❑ Orbital/eye prosthesis
- ❑ ❑ Any type of implant held in place by a magnet
- ❑ ❑ Any type of surgical clip or staple(s)
- ❑ ❑ Vascular access port
- ❑ ❑ Intraventricular shunt
- ❑ ❑ Artificial limb or joint
- ❑ ❑ Dentures
- ❑ ❑ Diaphragm
- ❑ ❑ IUD
- ❑ ❑ Pessary
- ❑ ❑ Wire mesh
- ❑ ❑ Any implanted orthopedic item(s) (i.e., pins, rods, screws, nails, clip plates, wire, etc.)
  Type: _____
- ❑ ❑ Any other implanted item
  Type: _____
- ❑ ❑ Tattooed eyeliner*

Please mark on this drawing the location of any metal inside your body.



**A small percentage of patients with tattooed eyeliner have experienced transient skin irritation in association with MRI. Therefore you must decide if this slight risk warrants undergoing your examination. You may want to discuss this matter with your referring physician.*

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

Patient's signature _____

MD/RN/RT signature _____Date _____

Print MD/RN/RNT name _____

Appendix 3

PHARMACY CODE 199 MEDICATION EXCHANGE TRAY CHARGE SHEET

Diagnostic Imaging Sciences Center
AA-038 Health Sciences Center
1959 NE Pacific
University of Washington
Seattle, WA 98192

Drug	Code	Amount	# Used	Expiration Date
Standard contents:				
Heparin 100 units/ml 10 ml Vial	1754	1		
Dextrose 5% 500 ml IV Bag	0087	1		
Dextrose 5% 250 ml IV Bag	0086	4		
Dextrose 5% 100 ml IV Bag	0475	2		
Sodium Chloride 0.9% 500 ml IV Bag	0108	3		
Labels		12		
Adenosine 6 mg/2 ml	3546	3		
Amiodarone 150mg Vial	4882	4		
Atropine Sulfate 1 mg/10 ml EMER Syr.	0342	3		
Calcium Chloride 1 gm/10 EMER Syr.	0381	2		
Dextrose 50% 50 ml EMER Syr.	0517	1		
Dopamine 500 mg Vial	1807	1		
Epinephrine 1 mg/10 ml EMER Syr.	2828	6		
Epinephrine 1 mg/ml 30 ml Vial	1812	1		
Lidocaine 2% 100 mg/5 ml EMER Syr.	0734	2		
Lidocaine 1 gm/250 ml Bag	4227	1		
Magnesium Sulfate 8 meq/2 ml	0138	3		
Metoprolol 5 mg/5 ml Vial	7193	3		
Norepinephrine 1 mg/ml 4 ml Vial	0728	5		
Procainamide 100 mg/ml 10 ml Vial	1923	2		
Sodium bicarb. 500 meq/50 ml EMER Syr.	2490	4		
Sodium Chloride 0.9% 30 ml Vial	1936	1		
Vasopressin 20 units/ml Vial	2013	2		
For DISC Contrast Reaction Kit:				
Albuterol Nebulizer	1199	1		
Atrovent Nebulizer	4998	1		
Benadryl 50 mg IV	1806	1		
Benadryl 50 mg PO	2183	1		
Needles		4		
Syringes 1cc		2		
Syringes 5 cc		2		

Appendix 4

Code Cart Lock Log for Cart # _____

Check actual lock numbers against last number documented on this sheet if numbers do not match, lock is missing or not intact, call Dispatch at 598-6040 to replace code cart. Send completed log to Materials Management Department 356018.

Date	Time	Lock Number	Initials / Area From	Comments

Code Cart Lock Log for Cart # _____

Check actual lock numbers against last number documented on this sheet if numbers do not match, lock is missing or not intact, call Dispatch at 598-6040 to replace code cart. Send completed log to Materials Management Department 356018.

Date	Time	Lock Number	Initials / Area From	Comments

Appendix 5

Code Cart Number:__ _____ **QA Date: _____**

Dept/Location: Dept. Radiology/DISC/AA-033 HSC **Checked by:_____**

Code 199 Cart Quality Assurance Check List

☐ I. Check to be sure that all locks are secured on code cart and that code cart has not been opened. Check to be sure lock numbers match the lock number recorded on Daily Code Cart Lock Log attached to the code cart. Check appropriate box below.

- ☐ A. Code cart opened – lock(s) missing.
- ☐ B. Code cart secure – lock(s) intact – lock number matches log sheet.
- ☐ C. Code cart secure – lock(s) intact – lock number does not match log sheet.

☐ II. Verify completeness of code cart.

☐ A. Break yellow lock(s) on code cart.

☐ B. Check to be sure all supplies and equipment are in the proper place.

1. Check supplies for expiration dates and verify the par.
2. Refill supplies needed using inventory Form 705001(LP9/9P), 705002(LP20).

☐ III. Check oxygen “E” cylinder.

A. If the pressure is below 1800 PSI (out of the green area on the gauge), replace the tank with a new one from the equipment storage room or gas cage.

☐ IV. Check to be sure that the Gomco suction machine on the top of the code cart is functioning properly.

A. Push the start button on the Gomco machine to be sure it works. Push the stop button to turn unit off.

B. Check the Gomco power supply to be sure it is plugged in to the back the unit and that the Gomco power supply is plugged in to the power supply on the side of the code cart.

C. Check to be sure that the suction canister is in place and complete with 2 suction tubes (the long suction tube should be attached to the top of canister marked “Patient” and the short suction tube should be attached to the top of the suction canister marked “vacuum”).

1. Replace canister if missing or incomplete. Remove plastic from blue lid and clamp securely on canister. Insure all tubes are connected properly as in step IV.C. above.

☐ V. Check to be sure that the Defibrillator is facing the back of the code cart and is plugged in to the power strip on the side of the code cart.

☐ VI. Check the clipboard for the following forms (in order listed below):

Appendix 5 (cont.)

A. 1 ea – UH0665 – Cardio Pulmonary Arrest Record
B. 1 ea – Cardboard (blank)
C. 1 ea – Code 199 Evaluation Sheet
D. 1 ea – UH0665 - Cardio Pulmonary Arrest Record
E. 1 ea – Code 199 ACLS Drugs Used in Adults

☐ VII. Check to be sure sharps container is not filled above full line on container.

A. Replace container if missing or items in container are above the fill line which is shown on side. To remove container:

1. Turn key in sharps container bracket.
2. Get new container from Equipment Storage Room. Snap lid securely in place.
3. Using key place container onto bracket and lock making sure container is securely in place.

B. Give used sharps container to Environmenal Services or place in MM Decontamination room for pickup.

☐ VIII. Check lift up tray on side of cart to be sure the following form is in the plastic pouch:
A. 1 ea – Code 199 ACLS Drugs Used in Adults

☐ VIX. Secure code cart with a yellow lock(s).
A. Check to be sure all drawers are securely closed.
B. Record all yellow lock numbers at the bottom on this form.
C. Record lock number(s) on Daily Code Cart Lock Log which is attached to the front of the code cart.

☐ X. Place a plastic cover over the cart.

☐ XI. Sign and date the top of the QA checklist.

Code Cart Lock Numbers: _____ _____

Appendix 6

Scanner Related Emergencies and Emergency Safety Procedures

Human Subjects

An emergency squeeze ball will be given with instructions for use. The subject will be monitored verbally throughout the procedure.

Emergency Stop

If there is an emergency, such as equipment failure that could cause injury, sparking of equipment or a fire, the operator or designee should immediately perform an emergency stop. **An emergency stop procedure is specific to each scanner and should be known by the MR operator prior to assuming any scanning duties.**

Medical Emergency

In case of a human subject, an employee or other personnel with a medical emergency (illness or injury), the following procedures will be followed:

- Assist individual out of the magnet room
- Call for assistance per procedure at that specific site
- Follow the institutional policies for that location

Magnet Emergency

If an individual is restrained or pinned by a ferrous object to the magnet, assess if the situation if life threatening. If YES, then,

- Initiate emergency rundown to quench magnet (see emergency quench below)
- Follow institutional policies for that location.

If an individual is restrained by a ferrous object to the magnet and is NOT in a life threatening situation, call for assistance to determine the optimal way of releasing the individual from the magnet field. If a quench is necessary proceed as above.

Report the incident as an accident and call for assistance to ensure ferrous object is removed from the field properly.

Emergency Quench

A quench includes the rapid release of cryogens and results in the loss or significant decrease of the magnetic field. A quench should ONLY be performed by authorized personnel with Level 4 training in dire emergency that involves a serious personal injury. Sudden loss of the magnet field in a quench situation could damage the magnet or components of the system. There is a considerable cost related to quenching the magnet and re-implementing the magnetic field. The strong magnetic field will dissipate in about a minute, release the individual.

NOTE: In extraordinary circumstances such as an earthquake or explosion, resulting in an uncontrolled quench, the oxygen level in the magnet room may significantly decrease possibly making breathing difficult.

Spontaneous Quench

On rare occasions an MR magnet may quench spontaneously and, in such event, there is the potential for air to be displaced downward by helium. In this event the O2 sensor alarm is triggered and an emergency exhaust fan will activate. Any persons in the magnet room should be evacuated immediately, and the door shut. The Director and Laboratory Manager should be called. Do not enter the room while the O2 sensor alarm is sounding.

In Case of Fire

The magnet room and equipment room are equipped with a clean agent gas fire suppression system. If a fire is observed in these areas all persons need to evacuate immediately and close the door.

There are pull boxes near the door of each room that can be utilized to manually release the fire suppression agent if the remote fire sensors have not initiated the dispersal sequence. The agent is not toxic and does not pose a risk to human life if breathed. As a backup, if a fire continues to progress, a temperature-sensitive water sprinkler system will activate.

Guidelines for Safe Operation and Conduct In the DISC MR Research Laboratory

Safety, defined as the absence of increased risk of injury or harm, in and around the MR scan equipment is of paramount importance and should be treated as the highest priority.

Safety in the MR area can be subdivided into two separate types that are inter-related. Both are important. The first is personnel safety and the second is equipment safety.

If a situation should arise that entails a decision between risk of damaging equipment or risk of jeopardizing personnel safety, safety of personnel is the first priority. That is not to discount the need to protect and maintain the MR equipment but only to stress the fact that personnel safety is the foremost concern and equipment comes second.

The best way to avoid accidents from happening is through safety awareness and proactive steps for prevention. The best method for promoting awareness and preventive measures is through education and safety training. Therefore, in order to prevent accidents and minimize the risk of endangering personnel or damaging equipment, all personnel who work in the MR Laboratory area, regardless of their job description, must receive a basic course in MR safety. This includes all MR Laboratory personnel, affiliate researchers who will come into the area, all coordinators and other study support staff, all students and graduate students working or studying in the area. In addition, all personnel working in and around the magnet room are required to take a more in depth course in magnet safety that includes:

- Handling of personnel, whether they be visitors, subjects or patients, in the magnet environment
- Screening procedures before people can enter the room,
- Safe and unsafe materials that can be taken into the room,
- Safe and unsafe materials that can be placed within the magnet during scanning,
- Strategies for preventing accidents and
- Steps to follow in response to an accident, should one occur.

The following policies are to be followed to insure a safe environment in the MR Laboratory and to prevent accidents from happening:

- Safety training must be completed for all personnel working in the MR Laboratory as outlined above. Successful completion of the required training course will be certified by the MR Technical Manager and such certification will be kept on file by the MR Laboratory Administrative Assistant.

- The MR Laboratory Manager shall meet with appropriate representatives of Seattle EMT/Fire Department and UW Campus police to familiarize them with the area layout and safety considerations when responding to an emergency situation in the Laboratory. This shall be done at periodic intervals to be decided through discussion with the respective departments but should be at least once per year.

All devices in the MR room or in the area immediately adjacent to the MR Room that could, potentially, be brought into the magnet room will be of non-ferromagnetic materials. This includes oxygen cylinders or other types of gas cylinders, which should be aluminum, and trashcans, which should be plastic or aluminum.

- No items that can be attracted into the magnetic field can be brought into the MR Room (even if it is not be used in conjunction with MR scanning) without first obtaining clearance from the MR Laboratory Manager or the Director of the MR Research Laboratory. If such devices are reviewed by the Laboratory Manager or the MR Director and found to be admissible but a safety risk for being attracted into the magnet, whenever feasible such devices will be placed on a strong tether that is no longer than necessary to place the device in the proper position for use, and this tether shall be strong enough to withstand the pull from a strong magnetic field without breaking.

- Should it be necessary to bring a metallic device such as a tool or monitoring unit into the room for maintenance or repairs, the bore of the magnet shall be covered by a protective plywood cover to prevent damage in the event the device is attracted into the magnet despite other safety precautions.

- Any device to be used in conjunction with MR scan operation must first be reviewed and cleared as safe for use by the MR Safety Committee.

- The person who is operating the scanner at any given time (defined herein as the operator) will be designated to be primarily responsible for safe operation of the MR room and equipment. This includes primary responsibility for clearing anyone from entering the room who has not been properly screened. All other personnel must yield authority for blocking room entry or stopping a scan for safety concerns to this individual, including the PI, the techicianss in the area, supervisors and others.

- All individuals will be screened prior to being allowed to enter the magnet room. For non-Laboratory personnel, including subjects, patients, visitors, this will entail clearance by a safety trained personnel who attests that there are no “red flags” (potentially unsafe conditions). In the event of a red flag issue, permission for the individual to enter the room may only be granted following review and clearance by the Safety Officer or the Laboratory Director.

- Anyone working in the MR control room and who will potentially be entering the magnet room during the course of their time spent in the Laboratory will remove all metallic items from their person so they can enter the room without hesitation or delay should the need arise.

- Individuals providing janitorial services will not be allowed in the magnet room unsupervised. Any cleaning to be done by non-MR Laboratory personnel is to be arranged ahead of time on a scheduled basis. Those doing the cleaning are to have undergone a safety training session as indicated above and safety screening plus they are to be supervised by the Laboratory Manager or a technologist.

- All visitors to the Laboratory must be informed of basic safety precautions and are not to be permitted in the room without first insuring they have removed all metallic items and all items that could possibly compromise safety for themselves or others in the room. They shall be informed of the need to prevent certain health-related items from entering the room that

could cause them harm such as surgically implanted devices especially those that maybe electronic such as cardiac pacemakers, nerve stimulators, cochlear implants or intracranial aneurysm clips. They should be queried in a general sense, being sure that they have none of these but will not be queried about details of their personal medical history that are protected by privacy rules.

- Any user found violating safety policies will be penalized. If a minor safety violation occurs, the individual will be issued a warning notice. Upon receiving two minor violation warning notices within one year, privileges will be revoked for that individual until such time as appropriate retraining takes place, and the Director of the MR Laboratory and the Laboratory Manager are satisfied that the deficiencies have been corrected and the individual has a paramount appreciation of the need for safety.

- If an individual creates a major safety violation, such as failing to screen a new individual prior to allowing them in the MR room, bringing unsafe equipment into the MR room without permission, or causing such equipment to be brought into the room, Laboratory privileges will be revoked immediately. They may be reinstated only following retraining and review as outlined above.

- All personnel working in the MR Laboratory without direct supervision, such as investigators from outside the MR Laboratory, graduate students working on a project, or off-campus personnel, will be responsible for any damage that may occur to the MR scanner or the Laboratory equipment as a direct result of that individual's gross negligence or misconduct. Prior to receiving permission to scan, they must complete and sign a form that acknowledges their acceptance of this responsibility. In the case of students and graduate students, this form must be signed by the Chair of their Department of record or an appropriate designee.

- Should any accident occur, this must be reported immediately to the Director of the MR Laboratory and the Laboratory Manager. A full, written report must be filed with the MR Laboratory Administrative Assistant within 24 hours of the incident. Such report should document the event, time, responsible individual at the time, individuals present, identity of the individual(s) injured or at risk, a brief narrative of what transpired along with any steps taken to mitigate the situation. This report must be signed by the individual primarily responsible for this event occurring

Certification for MR Operation in Human Subject Scanning (Animal Certification under separate SOP)

1. Introduction

This SOP seeks to define the types of MR operation involving human subjects at the Diagnostic Imaging Sciences Center (DISC) and to establish regulations that operators must meet in order to perform human subject scanning. The purpose is to meet or exceed clinical standards of care in the execution of research studies in the DISC lab at UW.

2. Definitions

2.1. Types of Subjects

Research Subjects: Human subjects or patients recruited for a research, clinical, or pilot study under an approved IRB protocol. This may include subjects with a clinical syndrome or condition, as well as healthy subjects, e.g. normal controls. These subjects are to be consented by study specific approved IRB forms and scanned only under projects approved by the DISC Operations Committee. All subjects must be medically stable and in no acute medical distress.

Normal or Test Volunteers: These are defined as human subjects volunteering for an MR scan to conduct basic methodological, pulse sequence, protocol development or equipment, coil or software testing. Subjects may grant consent under the general purpose Coil, Software and Device Testing IRB Consent Form. This general consent form is intended to be used for test purposes only and is not to be used for conducting a research study with serial subjects in lieu of a formal IRB approval process.

Normal control subjects for a research study are NOT considered “test volunteers.” If these volunteers are UW staff employees, the consent and safety screening can be kept on record for 1 year. Upon each re-scan, the MR safety screening is reviewed to verify there has been no change in medical history in the interval since the date of screening that may pose a safety risk to the volunteer. A new consent form is to be signed upon each new testing study and such consent is to be conducted and entered into the records. The DISC testing IRB is a flexible menu of possible scenarios. Consent forms signed for one purpose may not be used to apply for other circumstances.

2.2. Types of MR Operator Certification for Human Subjects

There are three levels of required training for scanning of Human Subjects. In descending order, these are:

General Certification: This is the highest level of certification, in which the individual meets qualifications to operate the MR scanner for any research protocol. Operators with general certification will have demonstrated proficiency equivalent to an RT. They are authorized to make safety determinations and serve as gatekeepers to Zones 3 and 4 non-MR personnel.

Study-Specific Certification: This level of certification will allow operation of the MR scanner for conducting one or more specific, pre-approved research studies. Operators with study-specific certification must gain approval for each new study before performing any MR scans under that study. Approval will be granted only after demonstrating proficiency in running the protocol for that study. Operators with study-specific certification will also be certified to scan test volunteers for similar types of MR exams/protocols. They are NOT considered authorized to make MR safety determinations if red flags are found without specific additional training and supervision; they may serve as gatekeepers to Zone 3 and 4 non-MR personnel.

Certification to Scan Test Volunteers: The most basic level of certification will permit operation of the scanner under limited settings with phantoms or normal volunteers, only. This level of certification is for protocol and methodological developments only, e.g. validating a new MR sequence. They are NOT considered authorized to make safety determinations and need prior MR safety screening approval (or form on record) from general certified staff, although with additional safety screening training, authorization can be given to screen volunteers.

3. Requirements for Certification

To achieve certification for operation of the MR scanner with human subjects, each operator must be trained and demonstrate proficiency in several core areas of MR safety, and involvement of human subjects. The minimum requirements for each level of certification are summarized in the following chart, which include both a core section common to all operators and a level specific training procedure described in Section 3.2. Definitions are listed in Section 3.3.

3.1. Chart of Minimal Requirements for Operator Certification for Human Imaging.

Operator Skill	Level of Certification		
	General	Study-Specific	Normal Volunteers
MR safety – human	X	X	X
MR safety – equipment	X	X	X
Emergency Response – human	X	X	X
Emergency Response – equipment	X	X	X
Database Training	X	X	X
Human Subjects Training (HIPAA, etc.)	X	X	X
Subject MR Safety Clearance	X	X[1]	X[1]
MR Scanner Proficiency	X	X	
Clinical RT Equivalency	X		

[1]Alternatively, subjects may be pre-screened by an operator with general certification CORE training requirements.

3.2. Specific Training Requirements

A. Core Certification

All staff certified to scan humans must successfully complete the core requirements as a prerequisite to hands-on training.

Magnet safety and Emergency Procedures (human and equipment)
Basic Scanning procedures (simulator time, familiarity with scanner operation)
Human SOP
HIPPA
BLS
Human Subjects Training

B. Certification to Scan Testing Volunteers

Satisfaction of the following requirements will permit this level of certification

5 Supervised human volunteer scans
1 hour coil training
2 hours scanner console operation training
2 hours data management
2 hours facility orientation and emergency procedures
1 hour cleaning procedure

C. Study-Specific Certification

Satisfaction of the following requirements will permit this level of certification.

7-10 supervised human scans on comparable study
1 hours coil training
2 hours scanner console operation training
2 hours data management
2 hours facility orientation and emergency procedures
1 hour cleaning procedure

D. General Certification

Satisfaction of the following requirements will permit this level of certification.

2 years of MR experience scanning human subjects with a variety of different protocols
120 human scans clinical RT equivalency
2 hours MR safety screening and extensive supervision
2 hours hardware safety and coil training
2 hours scanner console operation training
2 hours data management
2 hours facility orientation and emergency procedures
1 hour cleaning procedure

3.3. Definitions and Requirements of Operator Skills

MR safety – human: Demonstrated knowledge and understanding of MR risks to human subjects. Ability to screen and prepare subject for entry into the magnet room/bore. Has viewed all MR safety videos.

MR safety – equipment: Demonstrated knowledge and understanding of precautions needed to prevent damage to the MR equipment. Has viewed all coil/RF safety video. Read vendor safety info.

Emergency Response – human: BLS and CPR certification, demonstrated knowledge of emergency response steps, if appropriate for level of certification, contrast reaction training.

Emergency Response – equipment: Knowledge of circumstances that may require magnet quenching, emergency power interrupt, service calls, magnet down procedures and reporting.

Human Subjects in Research Training: Completed all University requirements for working with human subjects, such as the human subjects training course and HIPAA.

Human Interaction: Received training and demonstrated the ability to work with human subjects to ensure the subject remains calm, respectful of privacy, communicates effectively, non-coercive, recognize signs of claustrophobia and anxiety, judge the veracity of reported medical history.

MR Scanner Proficiency: Demonstrated ability to safely and competently operate the MR scanner, conduct the scan efficiently, resolve minor scan problems. Proficiency will be assessed by 7-10 supervised scans. Additional MR scan console time is available for extra practice time.

Clinical RT Equivalency: Completed the AART procedural requirements for certification for MR scanning: The Clinical Experience Requirements for MR consist of 53 procedures in 7 different categories. The 7 categories include:

A. Head and Neck
B. Spine
C. Thorax
D. Abdomen and Pelvis
E. Musculoskeletal
F. Special Imaging Procedures
G. Quality Control

Candidates must complete and document the performance of a subset of these 53 procedures according to the following rules:

1. Choose a minimum of 5 categories.
2. Choose a minimum of 4 different procedures from the selected categories.
3. Complete a minimum of 3 and a maximum of 10 repetitions on any chosen procedure.
4. Complete a minimum total of 120 repetitions across all procedures.

Each of the 120 procedures must be completed within the following guidelines:

- evaluation of requisition and/or medical record
- identification of subject
- documentation of subject history including allergies
- safety screening and subject education concerning the procedure
- subject care and assessment
- preparation of examination room
- select optimal imaging coil
- subject positioning
- protocol selection
- parameter selection
- image display, filming, and archiving
- documentation of procedure and subject data in appropriate records
- subject discharge with post-procedure instructions
- universal precautions
- MR safety procedures and precautions

and evaluate the resulting images for:

- image quality
- optimal demonstration of anatomic region
- proper identification on images and subject data
- exam completeness

4. Procedures for granting certification

All persons interested in certification should contact the MR Laboratory Manager to discuss the details of the process and to schedule required training sessions. After completing the core requirements arrangements will made to begin the hands on training for the level requested. Upon completion of all requirements and a satisfactory evaluation from assigned trainer, the DISC Operations Committee will review and grant approval if satisfied the applicant demonstrates competency.