RESEARCH WITH HUMAN SUBJECTS AT THE AIRC
UT Southwestern Medical Center – Advanced Imaging Research Center
Policy and Procedure Guide

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THE AIRC

Purpose
The Advanced Imaging Research Center (AIRC) provides a multidisciplinary environment for research in the imaging sciences. Although the early emphasis has been on advanced magnetic resonance methods, the long-term goal is to develop new imaging methods, to apply these methods to important questions in biology and medicine, and to train students, fellows and physicians. The AIRC is intended to serve investigators at the three University of Texas System campuses in the Dallas area.

Definitions
The term “researcher” or “research user” includes a Principal Investigator (PI) and any members of the research team performing research activities in the AIRC which may include a research coordinator, student, laboratory assistant or other staff member for whom the PI is responsible. All of these individuals must be IRB-approved study personnel and listed on the AIRC application.

The term “participant” or “research participant” refers to a human subject who is placed into the bore of the MR scanner for research purposes or a human subject participating in any research activities in the AIRC after enrollment into an IRB and PRC approved research study.

The term “operator” or “scanner operator” refers to one of three possible types of operators. First, an operator may be a licensed MR technologist employed by the AIRC. Second, an operator may be an employee of the AIRC who has completed special training and certification by the AIRC. Third, an operator may be a researcher trained and certified by the AIRC. Operator certification is specific for the instrument field (i.e., 3T or 7T). Furthermore, operators are certified either to operate a scanner for phantom or animal studies, or are certified to operate the scanner for human research studies. Operators have authority to stop any procedure deemed unsafe in their judgment.

Governance
The AIRC is governed by the following five-member board (or their designees): the Chief Academic Officer of UT Southwestern Medical Center (Chair), the President of UT Arlington, the President of UT Dallas, the President of UT Southwestern Medical Center, and the Chair of a relevant clinical department at UT Southwestern. The Board guides the overall direction of the Center. The Chief Academic Officer of UT Southwestern, with Board approval, sets policies for space and user fees. The Director of the AIRC, Dr. Dean Sherry, serves as a non-voting member of the Governing Board.

II. Research in the AIRC – Getting Started

New Research Grants
Before writing a new grant proposal for research to be done in the AIRC, PI’s are advised to contact Ms. Jeannie Baxter for general guidance on AIRC policies and feasibility for new proposed research in the AIRC.

Pilot Funding
Scan time may be available for gathering preliminary data for grant submissions. Requests for pilot funding are made to the Protocol Review Committee (PRC) via the AIRC Application for Human Subjects. If the researchers are requesting time for pilot projects, the PRC will recommend a priority score for support of pilot or other project time. A typical recommendation is ten hours of time on the scanner. When pilot time results in new grant funding or published research, please provide a report describing how the pilot time was helpful to your research.
III. Protocol Review Committee

Mission
PRC members evaluate all aspects of the experience of a research participant in the AIRC and make recommendations for policies to assure high standards in the protection of human subjects. All proposals are reviewed with an emphasis on safety for the research participants and staff and for feasibility within the resources of the AIRC. Additionally, all proposals for research are reviewed to assure high standards of scientific integrity.

Review Criteria
The following criteria will be considered in the review: 1) significance, 2) approach, including feasibility and technical resources required for the project (e.g., coils, operator, available scanning slots, etc.), 3) innovation, 4) investigators and the research team, 5) environment, including collaborations and support from the home institution, and 6) the likely impact of the project on future support. Projects with external peer-reviewed funding will be reviewed primarily for safety and feasibility. After review, there will be one of two responses: 1) approved or approved with stipulations, or 2) deferred with questions. If the application is deferred, the response will include the Committee’s concerns. If it is approved with stipulations, approval will require a response to Ms. Baxter addressing the stipulations.

Committee Members
Bryon Adinoff, M.D., UT Southwestern
Jeannie Baxter, R.N., AIRC
Ivan Dimitrov, Ph.D., AIRC
John Hart, M.D., Center for Brain Health, University of Texas at Dallas
Beverley Huet, M.S., Department of Clinical Sciences
Hanzhang Lu, Ph.D., AIRC and Department of Radiology
Craig Malloy, M.D. (Chair), AIRC, Departments of Internal Medicine & Radiology
Dana Mathews, M.D., Ph.D., Department of Radiology
Bart Rypma, Ph.D., University of Texas at Dallas and UT Southwestern

UTSW IRB and AIRC PRC Relationship
The UT Southwestern IRB must review and approve every project involving human subjects at the AIRC. While the IRB review will include evaluation of the entire project, the PRC review will focus on the practicalities of carrying out studies in the AIRC such as available resources and safety, as well as scientific interest. Although the IRB may choose to request information about the PRC review, the IRB review process is completely separate from the review by the PRC. Approval by the AIRC PRC does not guarantee a favorable review by the IRB. Approval by the IRB does not constitute approval by the PRC.

IV. AIRC APPLICATION SUBMISSIONS

Prior to submitting an AIRC application, please contact Dr. Craig Malloy or Dr. Hanzhang Lu to discuss the overall project, available equipment, and the resources necessary to carry out the project.

Please do not submit other material such as IRB paperwork, budget, grant application, etc. You may be asked for additional information during the review process.

The AIRC Application for Research with Human Subjects includes the following sections:
1. Research Introduction
2. AIRC Research Team
3. Experimental Conditions
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4. Purpose of the Study and/or Hypothesis to be Tested
5. Background and Results of Previously Related Research
6. Brief MR Analysis
7. Description of AIRC Procedures
8. Subject Selection and Number of Scans
10. Research Team and Collaborator Experience
11. Reference Citations

Getting Started

1. Submit your project to the UT Southwestern IRB. We recommend that this be done before submitting your AIRC application.

2. Submit an AIRC Application for Research with Human Subjects. Researchers may access the application via the AIRC website. Applications may be submitted while the IRB approval is pending. Please submit applications electronically to the PRC administrator Jeannie.Baxter@utsouthwestern.edu. For questions related to the submission process, please contact Ms. Baxter by email or phone 214-645-2726.

3. Assure that all researchers have suitable training for their work. This should include MR Safety Training for all researchers who will be performing research procedures and working with participants. For more information or to register for safety training, please contact Janet.Jerrow@utsouthwestern.edu.

4. Once your AIRC application is approved, submit the IRB approval letter, IRB approved Informed Consent Form and the HIPAA Authorization. The PI along with research team members working directly in the AIRC are required to attend an implementation meeting prior to enrolling the first research participant. Contact Ms. Baxter to schedule.

5. Contact Hanzhang Lu (3T studies) or Ivan Dimitrov (7T studies) for pulse sequence setup, fMRI stimulus testing (if applicable), and other technical support prior to enrollment of your first research participant. During this “setup” period, the magnet time used will not be billed to the investigator. It is necessary, however, to contact the AIRC for any magnet time requested for “setup” purposes to allow determination of eligibility and applicability. Usually, the setup takes less than three hours of magnet time. Note that the purpose of “setup” time is to resolve technical issues associated with the hardware and software at the AIRC.

Modifications to Approved AIRC Projects

Modifications to a project that requires changes to the IRB consent form, description of procedures used in the AIRC, inclusion criteria, or to researchers working in the AIRC must be approved by the IRB and PRC. An expedited review by the PRC administrator or evaluation from the PRC will depend on the nature of the changes. The modification form is accessible from the AIRC website.

Closing an AIRC-Approved Project

When a project has been completed or is no longer active, please send a summary of study results along with a notification of study closure by email to Jeannie.baxter@utsouthwestern.edu.
V. ZONES AND SUPPORT ROOMS

The MR area is divided into four zones. This classification, suggested by the American College of Radiology, is commonly used in discussions about MR safety and for this reason is described here briefly. Zone I includes all areas that are freely accessible to the public such as the waiting rooms and adjacent restrooms. Zone II is the interface between publicly accessible areas and the restricted access Zones III and IV. Research participants are greeted in the waiting room and escorted into Zone II, which includes the connecting hallways, interview rooms, and the mock scanner. Participants must be escorted by trained personnel in Zones II, III or IV. Zone III refers to the area in which access by unscreened personnel is not allowed and introduction of ferromagnetic objects or equipment is severely restricted. Within the AIRC, Zone III refers to the control rooms and equipment rooms of the 3T and 7T systems. Zone IV is the magnet room itself. Only personnel trained at Level 2 are allowed into Zone IV without escort.

Badge Access
MR Safety Training taught by AIRC personnel is required for ALL badge access to the AIRC. Access will be given only to areas required for a specific researcher’s work.

Researchers working with phantoms in restricted zones will require operator certification by Dr. Lu (3T scanners) and Dr. Dimitrov (7T scanner).

Researchers seeking access to work with research participants must also be listed as study personnel with the UTSW IRB and listed on the AIRC approved application.

Researchers without a UTSW badge must be approved for a visitor badge. Complete the top portion of the form Application for Visitor ID/Access Card (Appendix A) and submit to AIRC administration for initial approval. The approved form must then be taken to the UTSW Visitor Center to obtain the visitor badge.

Task Training and Interview Rooms
Rooms are available for consenting, screening and training research participants prior to an MR exam. All rooms are bookable in the online scheduling system and will not incur a fee for use. Rooms are designated for use as follows:

Training 1 (NE2.804) is located within the 3TA suite and is specifically designated as an fMRI task training room.

Training 2 (Mock Scanner) includes both the mock scanner and the adjacent training room. It is best used for training that requires no distractions and/or for training that includes use of the mock scanner.

Training 3 (NE2.730) is together with the dressing and waiting area near the 3T scanners and is best for consenting, screening and short task training. It is not acceptable for task training when noise is a distraction. Blood draws and IV starts may be performed here.

Dressing Rooms and Lockers (NE2.730) are designated areas for securing a research participant’s personal belongings during 3T exams. Please utilize these areas for storing clothes, shoes and a participant’s valuable items.
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Interview 1 (NE2.820) is reserved for use with the 7T scanner. It has an exam table and may be used by physicians for participant assessments. Blood draws and IV starts may be performed here.

Interview 2 (NE2.732) is located within the 3TB MR suite and is specific for short task training where noise is acceptable. It is also suitable for blood draws and IV starts.

Procedure Room (NE2.810) is primarily for research procedures with an MR component. The Procedure room may be booked with prior approval of the PRC administrator.

Mock Scanner
The mock scanner is a valuable resource to assess a participant’s level of comfort or claustrophobia. Researchers may also use the mock scanner to train or prepare a participant for an MR procedure. It is booked through the online scheduling system and is available to researchers at no additional charge.

VI. Training

MR Safety Training
Our highest priority is safety for participants, safety for all researchers, and safety for other individuals in the area; therefore, AIRC-provided MR safety training in a classroom environment is required for all new researchers.

Level 1 Training provides the basics of MR technology and safety and provides minimal information needed for individuals who are restricted to the control room for the purpose of observing a study or receiving an explanation of the operation of the system.

Level 2 pertains to researchers working in the magnet room. The intent of the safety training is not to achieve expertise as a licensed MR technologist; however, any person working in Zone IV should be aware of proper positioning of the research participant, the importance of thermal and acoustic safety, and the importance of preventing direct neurovascular stimulation. Following the classroom training, new researchers will have a brief tour of the MR scanners and support rooms.

Training is provided in a 30-minute presentation followed by a brief quiz. Annual renewal is required during the month of May for each year following initial training and can be completed online.

The PRC administrator will maintain a roster of current training status. All persons in the control room must have their ID badge immediately available. Any person who seeks training accepts responsibility for his or her own safety. The AIRC assumes that any person who chooses to work in the magnet room does not have implanted metal contraindicated for work in the area.

Prior Training at Other Institutions
Although investigators may already have considerable experience and safety training, AIRC training is required. There are no waivers for prior experience.

7T Safety Training
Researchers working with research participants in the 7T MR suite will require additional training. The operator and a second trained person must be present during all 7T scans with research participants. Basic MR Safety Training must be completed before scheduling 7T Safety Training.
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Operator Training
Researchers desiring to operate a 3T or 7T scanner must be trained and demonstrate competency. They must have knowledge and demonstrate the ability to respond appropriately to emergency situations. Contact Hanzhang Lu for 3T certification and Ivan Dimitrov for 7T certification. Operators will be trained in safe operation of all components of MR technology and are responsible for securing the area during and after use of the scanner.

Basic Life Support (BLS)
All operators must provide a valid copy of Basic Life Support (BLS) certification from an American Heart Association Healthcare Provider Course. Certifications are valid for two years and must be renewed in a timely manner in order to retain operator status.

VII. OPERATIONS

Instrument Availability
The 3T scanners are available for operation 12 hours a day (8 A.M. to 8 P.M.), Monday through Saturday, and on Sunday from 1 P.M. to 7 P.M. Note that AIRC technologist availability is different from instrument availability.

Research participants may be scanned on the 7T instrument during ordinary work hours which are considered to be Monday through Friday, from 8 A.M. to 5 P.M. Off hours are considered to be any time outside of ordinary work hours, including University holidays.

In determining schedules for scanning participants, the PI should consider that the AIRC is not physically connected to any emergency care facility. Emergencies in the Clements Imaging Building during off hours are handled by the Dallas EMT/fire department. Thus, careful review of off-hour scanning requests will be made by the PRC.

In general, any study involving a research participant with more than a minimal risk of a medical adverse event or any study involving administration of any drug or contrast agent must be performed during ordinary working hours of UT Southwestern. Although the researcher may make an assessment of their subject population and give a recommendation to the PRC, ultimately, the PRC will determine case-by-case which participants may be scanned during off hours.

Technologist Assistance 3T
An AIRC technologist will be available for scanning on 3TA from 8 A.M. to noon and 1 P.M. to 6:15 P.M. on ordinary workdays. The 3TB scanner has AIRC technologist coverage Monday through Friday from 8:00 A.M. to noon and 1 P.M. to 4:45 P.M. An AIRC technologist is also available for 3T scanning on Saturdays. During this “tech-covered” time, it will be the AIRC technologist’s responsibility to perform or supervise the performance of the MR scans. The AIRC technologist may, at his or her sole discretion, request physician supervision during any scan.

AIRC scanners must be operated by an AIRC technologist or an AIRC-approved operator certified by either Hanzhang Lu (3T) or Ivan Dimitrov (7T). Approved operators must maintain and provide documentation of Basic Life Support (BLS) certification.

During off-hour scans, the operator and at least one other person must be in the control room. The only exception is if Dr. Lu or an AIRC technologist is operating the system. Other exceptions to this rule may be requested and must be approved by the PRC.
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Delays
To avoid potential delays, it is strongly recommended that research participants arrive at the AIRC at least 30 minutes in advance of the scheduled MR scan time to allow for screening and preparation for the scan. Many research participants with an illness or more complicated MR procedures will require extra time prior to approaching the scanner. Thank you for considering this time when informing your participant of their scheduled appointment time (which is different from the scheduled scanner time). If an appointment is delayed more than 15 minutes, the AIRC technologist will determine whether a delayed scan start can proceed.

Operator Requirements for 7T
Two individuals with Level 2 training must be present in the 7T control room at all times when a participant is in the scanner. Both persons are also required to have specific training related to 7T emergency procedures. An AIRC research nurse or AIRC technologist will screen all participants. The operator must also review the MR screening form prior to the scan.

Atypical Findings in Research Data
MR procedures in the AIRC are solely for research and are not intended for medical diagnosis or medical treatment. When a scan reveals a suspected abnormality or irregular finding, the following procedures are applicable:

1. The operator will inform the researcher accompanying the participant at the time of the scan.

2. The operator will complete the AIRC Research Subject Atypical Finding Report Form (Appendix B). Please complete and return this form to the PRC administrator within 3 business days.

3. PRC administration will send notification of the atypical finding in writing to the PI. The AIRC Medical Director will also be informed.

4. It is the PI’s responsibility to notify the participant of the potential finding with a recommendation for follow up with the participant’s healthcare provider.

MRI exams in the AIRC are for research purposes and not for clinical interpretation or diagnosis. The IRB and AIRC PRC recommend a statement to this effect be included in the IRB consent form. Upon request, applicable language will be provided.

Reporting
The operator is responsible to provide information to the PRC administrator or the AIRC Medical Director as follows:

- Immediately report any injury or incident or near incident pertaining to a projectile object by completing the MRI Machine Incident Report Form (Appendix C).

- Using the Research Subject Adverse Event Report Form (Appendix D), report unanticipated or serious adverse events.

- Report unusual or atypical findings by completing the AIRC Research Subject Atypical Finding Report Form (Appendix B).
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- Immediately report equipment damage or malfunction to Hanzhang Lu (3T) or Ivan Dimitrov (7T). After-hours phone numbers are listed in all control rooms.

- Report any circumstance in which a protocol was not followed as approved by the PRC.

Quality Control
AIRC staff will perform periodic quality control studies. The scans will consist of conventional T1 and T2 scans as well as EPI dynamic scans. The SNR, ghosting level (percentage of ghosting relative to the static signal) and temporal stability will be evaluated and made available to research teams as requested. Users are encouraged to report unusual image results to AIRC staff.

Available Protocols
Standard MRI protocols will be available on the scanner and saved in a folder named “AIRC protocols.” Researchers are welcome to use them as needed, but please do not change these protocols. Individual folders may be created by Researchers under the “User defined” directory in which their optimized protocols can be saved. At the beginning of a project, the researchers will typically copy certain standard protocols and make customized modifications. These optimized protocols will be saved in individualized folders for future use. Detailed protocols are included in the “Available sequence” section and can be found on the scanner console.

Protocols from Other Sites
There are two levels of protocol transfer. If the to-be-transferred protocol uses a pulse sequence that is present on our scanner, then the transfer would only involve setting up the scan parameters to maximally match the original protocol, which can be easily done by AIRC staff or a qualified investigator. If the new protocol requires the use of a customer-designed pulse sequence, then pulse sequence programming would have to be performed. The investigator, if qualified, is welcome to program the pulse sequence but please contact the AIRC staff before attempting to test it on the MR system. If an investigator is not able to program a pulse sequence, then it would depend on the expertise and the availability of the AIRC staff to implement the pulse sequence for the investigators. Note that using a Philips pulse sequence obtained from another Philips site does not necessarily make implementation easier because different sites may have different software versions, hardware configurations, coil availability, etc. Very often, the pulse sequence would need to be re-implemented even if it has been operational on another Philips system. Overall, prior to any protocol transfer, consultation with the AIRC staff is highly recommended.

Integrating Stimulation Protocols with Scanning
A group of standard fMRI related equipment is available, including visual stimulation, response button boxes, audio stimulation, E-prime software, eye-tracking system and a mock scanner. The AIRC staff is responsible for maintaining and updating these devices. If researchers are interested in using these devices, please contact the AIRC staff for a training session.

New Devices in the Scanner Environment
The investigator may have a project-specific device. It is crucial to discuss these devices with the AIRC staff as early as possible and test the devices extensively before bringing them into the magnet room. There are a number of concerns. For example, the devices may be damaged by magnetic fields, the devices may cause interference and image artifacts, the device could injure the participant through heating or other electrical effects, or the device could become a projectile. Either Dr. Lu (3T) or Dr. Malloy (7T) must personally approve the use of any device.
VIII. Scheduling

Online Scheduling System
All research participants studied on the 3T and 7T scanner must be scheduled on the online scheduling system using the approved AIRC application number. The scheduling system is running on a University server and will allow the researcher to view, add, cancel and change the scanner schedule. Scheduling is accessible from any computer (within UT Southwestern or outside UT Southwestern) connected to the internet. A username and password is required to log into the program. Each PI will be assigned a user name and password. The PI may share the username and password with other members of the research team delegated to scheduling participants with the understanding that scheduling will be performed within AIRC guidelines. An individual PI may have more than one project at the AIRC, but only one username will be assigned per principal investigator.

To schedule a scan, go to https://swsairc.swmed.edu. Scheduling for approved projects is on a first-come, first-served basis up to 12 months in advance. A research participant’s name, birthdate and phone number may be used to reserve a spot while scheduling is in process; however, “phantom” holds are not permissible to hold random spots in the scheduling system for research participants. Improper scheduling may result in suspended scheduling privileges.

Administrative Holds
Administrative holds are scheduled by the PRC administrator and may be used or released as needed by the scheduling administrator. Generally, these are reserved for maintenance of the scanners or for projects that require scheduling within a short amount of time due to inclusion criteria pertaining to surgery, presentation of symptoms, etc.

Conflicts and Priorities
AIRC operations flow according to the online scheduling system. Researchers may coordinate with each other to accommodate special situations of scan scheduling. It is the researcher’s responsibility to communicate with each other for such arrangements. Any mutually agreed changes in the schedule must be recorded into the log book for proper billing.

Scheduling Exceptions
Exceptions to the scheduling policy may be requested by submitting a written statement in explicit terms (e.g., special subjects must be flown in from remote locations, special grant stipulations, etc.). The PRC will review all requests, and an investigator-specific policy may be formulated.

Scheduling Restrictions
There are many investigators using AIRC scanners and everyone has deadlines for their research. Consequently, a ten hour maximum number of hours may be scheduled per investigator in a given week. This number may be adjusted periodically in seasons of high use. An email will be sent to the AIRC listserv to keep all researchers up-to-date on scheduling restrictions.

IX. BILLING AND CANCELLATIONS

User Fees
User fees are set by the AIRC Governing Board. The PI is financially responsible and will be invoiced once per month based on information entered into the scanner log book. Failure to pay applicable charges may result in the suspension of the user account and the use of the AIRC facilities.
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The current rate for the 3T scanners is $500 per hour. The current rate for the 7T scanner is $750 per hour. Billing and scheduling are based on quarter-hour increments (i.e., $125 per 15 minutes) with a minimum of 30 minutes. Billing begins and ends when a participant enters and exits Zone IV. Time spent by the operator setting up coils for the scan and time spent archiving data will not be billable. Please note that time charged is not based on the online scheduling system.

Cancellations
The cancellation policy is applicable during all operational hours Monday through Friday. The same cancellation policy will apply to all researchers utilizing the AIRC technologist on weekends and University holidays, except when the Researchers operate the scanner without an AIRC technologist.

Cancellation of a slot should be done at least 24 hours before the start of the scheduled scan. If a scan is cancelled within 24 hours of the scheduled start time, the investigator will be charged a $100 fee. If another investigator can use the time, the cancellation will not incur a charge.

Please cancel a training or interview room if not needed as a result of a scan cancellation.

No-Show Cancellations
If a research participant does not make an appointment, the investigator will be charged a $100 fee. However, if another investigator can use the time, the investigator will not be charged.

Aborted Scans
If a participant is found to be claustrophobic or the scan cannot proceed for other reasons after the operator has attempted to position the participant, the PI will be charged based on the actual time used or 30 minutes, whichever is greater. Researchers are encouraged to use the mock scanner in advance of the scheduled appointment time to test whether their participants are claustrophobic or otherwise suitable for an MR procedure.

X. POTENTIAL RISKS AND SAFETY PRECAUTIONS

Promoting a Safe Research Environment
Researchers and operators are together responsible for safety of the research participant and the safe operation of the instrument. The AIRC technologist is responsible to perform or supervise during “tech-covered” scans. During a scan, the technologist will consult with the researchers, as needed; however, if the technologist determines the study is in any way unsafe or inappropriate, the study will be stopped. At other times when an AIRC-approved operator is running the scanner in the absence of a technologist, the instrument operator is in charge. The PRC or the PRC Chair has the discretion to rescind approval of any research protocol for violation of AIRC policies and procedures. Research in the AIRC is subject to all relevant institutional policies at UT Southwestern, including all IRB policies. Selected topics are emphasized in the following section.

Pregnancy
To-date, there are no known harmful effects related to the use of MR procedures during pregnancy (Sawyer-Glover and Shellock, 2000); however, current FDA guidelines state that safety has not been established for imaging the fetus. Consequently, women who suspect that they are pregnant are not eligible for an MRI for research purposes. Age range and gender distribution of participants should be provided in the IRB and AIRC applications, along with methods to exclude pregnancy (questionnaire, urine or serum pregnancy test, gender/age restriction, etc.). Pregnancy tests are available at no additional charge.
Scanning Minor Participants
Participants under the age of consent must be accompanied by a parent or guardian. If the parent or guardian enters Zone IV with the participant, an MR screening form is required.

Screening for Metal Hazards (Static Magnetic Field)
To prevent accidental introduction of metallic objects into the magnet room, all portable metallic or partially metallic objects allowed in the control room must be identified as MR Safe, Not MR Safe or MR Conditional with the conditions clearly identified on the object. Fire extinguishers, oxygen tanks, wheelchairs and fMRI equipment are examples of devices that require verification. Under no circumstance should any metallic object be taken into the magnet room unless it is clearly labeled or otherwise known to be non-ferromagnetic and MR safe. Never assume MR compatibility.

A research team member trained at Level 2 must accompany every research participant in restricted access areas. All participants are required to sign the Magnetic Resonance Procedure Screening Form for Subjects prior to any MR procedure. This also applies to persons who may accompany a participant in Zone IV during a scan. A screening form is valid on the day of the procedure; therefore, any follow-up scans on a different day will require a new screening form.

Any participant undergoing a scan must remove all personal belongings and devices. These include, but are not limited to, hearing aids, jewelry (including body piercing), contraceptive diaphragms, cosmetics containing metallic particles, pagers, cell phones, and clothing items that may contain metallic items or thread.

Screening for the 3T Scanners: Research participants with implanted metal or medical implant devices may not be eligible for a research scan at 3T. Metal implants should be documented on the screening form and determined to be safe by the operator before undergoing any MR procedure. Some medical devices are absolute contraindications and may include, but are not limited to, neurostimulation devices, pacemakers, and hemodynamic support devices.

Screening for the 7T Scanner: Screening of the participant is essential following established safety guidelines established in the AIRC. The safety of metal implants at 7T has not been systematically investigated. Therefore, research participants with metal implants or implanted medical devices are not to be scanned at 7T.

RF Hazards
Exposure to RF energy may cause tissue heating. The scanner is programmed to function within FDA specified limits. For this reason, the operator must accurately indicate the participant's age, weight and gender before scanning since these parameters are included in limit computations. Participants with diabetes, hypertension, impaired cardiac output, obesity, are elderly or have fever or any impairment in the ability to perspire may have a reduced capacity to disperse heat and should be studied with care under IRB approval.

Gradient Field Effects
Acoustic Noise: All participants must use hearing protection during any imaging in the MR scanners. A participant has the right to end the study at any time if the acoustic noise is not tolerable.

Peripheral Nerve Stimulation: Some protocols have the potential for inducing PNS or peripheral nerve stimulation during the scan. The usual precautions should be followed during all scans. For example, instruct the participant to inform the operator if they experience discomfort or pain. Instruct the participant not to cross arms or legs in the MR scanner. Be in constant contact with the participant.
Research with Human Subjects at the AIRC

Stop the scan if the participant complains of severe discomfort or pain. Report any incident involving discomfort or pain to the AIRC Medical Director.

Confidentiality and Protecting Health Information
No names, social security numbers, research study numbers or any identifiers will be entered into the scanner console. The operator is responsible for entering the consecutively numbered exam ID and other pertinent information into the log book. It is the responsibility of the researcher to make note of the exam ID.

Although no identifiers are stored in the computer, certain PHI is necessary for carrying out research in the AIRC. Researchers are advised to include the AIRC in the IRB HIPAA Authorization under “Will my protected health information be shared with someone other than the researchers?” This will disclose that certain information will be shared with AIRC personnel and is directly related to the conduct of the research.

It may be necessary for other research teams to be in the control room or support rooms during a scheduled research scan. Please keep operator interruptions to a minimum and speak quietly in the area so that research in progress is not delayed or otherwise negatively impacted. Of course, all researchers are expected to respect the privacy of our research participants.

Contrast Agents
Studies requiring contrast-enhanced MRI must have PRC and IRB approval. AIRC technologists and registered nurses trained to initiate and attend peripheral IV lines may administer IRB-approved contrast agents as directed by a licensed physician. The physician must be immediately available inside the Clements Building to intervene should a participant experience complications during an MR scan with contrast. The IV Contrast Administration Record (APPENDIX F) must be completed by the researchers and the AIRC technologist.

There is a small risk of Nephrogenic Systemic Fibrosis (NSF) related to gadolinium contrast agent administration. An eGFR calculated within six weeks of the procedure is required for all participants receiving gadolinium. AIRC protocols approved for contrast administration will receive AIRC Guidelines on the Administration of IRB-Approved Non-Iodinated Contrast Media with their project approval.

XI. MEDICAL EMERGENCIES

All researchers must consider how their group will handle a medical emergency before scheduling any participants for an MR procedure. As appropriate, this plan must identify research team members responsible for removing and caring for an uncooperative or unconscious participant from the magnet room. All personnel should be familiar with the following procedures in the event of an emergency:

1. **Remove the participant and scanner bed from the magnet room.** Remove the participant from the magnet room so that the Emergency Response Team need not enter the magnet room. Never take CPR equipment into the magnet room.

2. **Initiate CPR if indicated.** Stay with the participant.

3. **Contact emergency services.** The Ambulatory Services Emergency Response Team (ERT) is available Monday through Friday, 8 A.M. to 5 P.M. From a
The nature of the emergency: This could be cardiac arrest, seizure, severe drug reaction, respiratory arrest, etc.

- The location: Give the room number of your location. All locations are posted on the wall in the MR control rooms.

- For an ambulance, ask the dispatcher to activate Emergency Medical Services (EMS). After 5 P.M. and on holidays, weekends, or inclement-weather days, use a campus phone to call University Police at 911. Do not use a cell phone. The University Police know the campus and can quickly direct EMS to the participant.

4. Locate Emergency Supplies. An emergency drug box and oxygen are located in the 3TA control room. An AED is located in the hallway outside the 3TA control room. All researchers with AIRC badge access will be given access to the 3TA control room.

5. For Contrast Studies, Contact the Research Physician. The physician will assume responsibility for managing the emergency.

6. Other Responsibilities of Research Personnel. Alert the Rogers clinical MRI staff of the situation and the location of the participant. Post one person at the entrance to the Rogers MRI to direct the response team into and through the clinic to the participant. Contact the AIRC Medical Director to request assistance. Go to and remain at the scene of the emergency; be ready to help until enough ERT members arrive.

XII. HARDWARE

The 7T Scanner
The Philips Achieva 7.0T system is a Magnetic Resonance Imaging system designed for ultra-high field imaging and spectroscopy research. It is restricted to investigational use. It is not intended for use as a diagnostic or medical device. At this high field, scan protocols need to be optimized for the 7T; this is a primary responsibility of the user. The behavior of the radiofrequency excitation pulses differs at 7T compared to 3T. Therefore, the user must also consider r.f. inhomogeneity in the study design.

The 3T Scanners
The two 3T systems are equipped with QUASAR dual high performance gradient coils capable of a maximum gradient of 80 mT/m and a slew rate of 220 mT/m/ms. The scanners have multiple-receiver systems (3TA with 16-ch and 3TB with 32-ch) capable of parallel imaging, including sensitivity encoding (SENSE) technique first developed by Philips Medical Systems. The image reconstruction computers are capable of up to 1200 images per second, allowing real-time fMRI data processing on the scanner console. The patient bore diameter is 60cm with a length of 60cm, and can support patients weighing up to 300 lbs. The following RF coils are available on the system: body transmit-receive coil, 8-element SENSE head coil, 32-element SENSE head coil, transmit-receive quadrature head coil, 12-element CTL spine coil, 6-element cardiac coil, 4-element torso coil, two-channel 14cm surface coils, two-channel 20cm surface coils, 8-element knee coil, 16-channel neurovascular coil, and
4-channel breast coil. 3TA is also equipped with a broadband multi-nuclear spectroscopy and imaging RF amplifier covering 10-130MHz. A $^{31}$P loop coil is available for multi-nuclear spectroscopy studies. The systems are maintained by the vendor under a service contract.

Available Sequences
The available sequences include gradient-echo, spin-echo, echo-planar-imaging (EPI) for fMRI, diffusion imaging including online ADC calculation, turbo-spin-echo sequence, GRase sequence, inversion recovery (e.g. MPRAGE), black-blood sequence, water/fat-selective excitation, balanced fast field echo sequence, time-of-flight angiogram sequence, phase-contrast angiogram sequence, partial Fourier, rectangular field-of-view, partial scan percentage, keyhole, cardiac-gated breath-hold fast field echo, magnetization transfer sequence, single-voxel spectroscopy, chemical shift breath-hold, multi nuclear spectroscopy, and a variety of prepulses (e.g. saturation preparation, inversion preparation, REST slab).

Available R.F. Coils
Quadrature transmit and receive body coil, quadrature transmit and receive head coil, 8-element SENSE receive-only head coil, 32-element SENSE receive-only head coil, 12-element CTL receive-only spine coil, 6-element SENSE receive-only cardiac coil, 6-element SENSE receive-only torso coil, 2-element SENSE receive-only Flex-M coil, 2-element SENSE receive-only Flex-L coil, 8-element SENSE receive-only knee coil, 4-element SENSE receive-only breast coil, and 16-channel SENSE receive-only neurovascular coil.

Physiological and Visual Monitoring
The facility provides 42-inch plasma screens to monitor the participant, 2-CCD cameras mounted on the wall of the magnet room, adjustable fresh air supply and variable lighting, in-bore microphone and ceiling-mounted loud speakers supporting bidirectional participant-operator communications, music entertainment for the participant, peripheral pulse, respiratory pulse, vector ECG, display of these physiological signals on the operator’s console monitor, and use of these physiological signals to trigger and/or gate the MR scanning.

Connectors on the Penetration Panel
The following connectors are available: 8-inch waveguide on the back of the magnet room for the penetration of video projector, two 5-inch waveguides (one on the front of the magnet room and the other on the back) for penetration of other non-metallic tubes, medical gas line penetrations (1/2 inch x2, 3/4 inch x1), and multiple filters on the RF shielded room for penetration of metal wires.

Gases in the Scan Room
No cylinders (metallic or non-metallic) are allowed in the magnet room. Medical gas administration should be supplied via the penetration waveguide from outside the magnet room.

Power Injector for Contrast Agents
IRB-approved MR contrast agents may be administered to the participant by an AIRC technologist or a licensed nurse trained to operate the power injector. The power injector and accessories are available for the 3TA scanner; however, it is the researcher’s responsibility to provide the contrast agent for injection. It is also the investigator’s responsibility to determine the appropriate dosage and injection rate and acquire approval from the UTSW IRB and AIRC PRC. AIRC technologists and nurses are available for IV starts and may be scheduled by emailing AIRC administration.
Research with Human Subjects at the AIRC

Stimulus Presentation Equipment
Visual stimulation is presented by back-projection from a high-resolution video projector (Epson 7000 series) with a long throw lens with adjustable zoom. The visual stimulation signal is generated and controlled by a program running on a computer (PC, Macintosh, desktop, laptop). Stereophonic audio stimulation is delivered through dual channel air coupled transducers using a customized headset that selectively blocks the scanner noise. Alternative video and audio sources include CD player, VHS/DVD player, cassette tape player and am/fm tuner, integrated through a system control center. Four fiber optic button-boxes are connected to the stimulus computer to allow the recording to participant responses during the fMRI experiment. Additional fMRI related equipment includes an MR-compatible eye-tracking system and a full size mock scanner with simulated sound, vibration, airflow and stimulation.

Data Storage and Transfer
A UNIX data server (Sun Microsystems, Mountain View, CA) is available for processing and data storage. It also has a tape drive to backup the data on a regular basis. The data server is connected to the scanner console so the MRI data on the console can be transferred to the server via ethernet. The data server has a total of four terminals and researchers are welcome to use the terminals to access and/or process the MRI data. The data server is also accessible via secured internet connection from outside the UT Southwestern Medical Center. The user account management will be the responsibility and authority of the AIRC.

Equipment for Non-Ambulatory Participants
An MR-safe wheelchair is available for emergency transport or for ambulatory participants needing minimal assistance. Otherwise, the AIRC is not equipped to handle non-ambulatory participants.

XIII. SOFTWARE

Current Software Description and Version
Scanner control from the operator’s console is based on a PC hardware and Windows XP operating system. Some features are 2.8 GHz dual Intel Xeon processors, 3GB internal memory, 36GB system disk, 36GB data storage disk (for approximately 250,000 256x256 images), 19 inch LCD color monitor, a two-way intercom for communication with the participant, and ethernet connection via 100BaseT connections. The external storage device includes a MOD R/W device for 4.1GB disks. The scanning software is currently running on Philips software package version 1.7. A variety of special software packages is also available for a particular category of scanings, which includes NeuroPlus Package, BodyPlus Package, BreastPlus Package, OrthoPlus Package, CardiacPlus Package, AngioPlus Package, OncoPlus Package and PediatricPlus Package. These packages have pre-defined scan protocols and post-processing capabilities. A ViewForum workstation is also available in the 3T control room for viewing and processing of the data. The ViewForum’s user interface is almost identical to the scanner console (without the scanning functionalities) and its functionality includes standard interactive windowing, window presets, geometry manipulations, stack and tile viewing, cine, movie-export, sequence generation of volumes and projections, multi-dimensional data set sorting, linking, annotations and measurements.

Raw K-Space Data
Saving of raw k-space data is feasible but not routine. Certain special parameters need to be activated before the scan is performed. After the scan is finished, special data export procedures are needed to save the k-space data. If the scan is performed without the appropriate parameter settings, there are no means to recover the k-space data in post-processing.
Data Processing Software

Online data viewing and processing on the scanner console, offline data viewing and processing on the ViewForum workstation, offline data processing on the UNIX data server (software includes MATLAB, SPM, AFNI, FSL, AIR, ImageJ), offline data processing on one of our desktop PCs in the control room and the mock scanner suite (software includes MATLAB, SPM, ImageJ, MRicro, DicomWorks).

XIV. DATA MANAGEMENT AND ANALYSIS

Data Backup by the AIRC

A UNIX-based data server is maintained by the AIRC staff. The image data from the scanner can be transferred to the data server via network. All data on the data server are backed up on a regular basis to a tape drive. Researchers are welcome to use the data server for storage of their data acquired at the AIRC. However, the use of storage for data acquired at other facilities should be minimized. The data storage on the server is accessible by using one of the four terminals of the server, or by using remote login using SSH or SFTP. Every attempt is made to allow the data server to store as much data as possible and to keep them as long as possible. The investigator should copy the data to their own storage device (CD, DVD, hard drive etc.) in a timely manner and certainly within 6 months after the acquisition. It is the investigator’s responsibility to store and safeguard their data.

Data Transfer to Your Lab

Several approaches are available to transfer the data from the scanner to the investigator’s own lab. 1) The data on the scanner console can be directly copied to a DVD or a USB memory via a built-in drive. 2) The data can be transferred to the data server and then remotely downloaded via a network connection (e.g. SFTP, Port #10022).

File Formats

Two general file formats are available: 1) Philips REC/PAR file pairs. The REC/PAR files are Philips-specific file formats that are used to store MRI data. The REC file is a binary data file that contains continuous streams of 16-bit signed integers. Note that only 12 bits of the 16 available bits are used. As a result, the values can only range from 0 to 4095 (212 different values), rather than from 0 to 65535. To some extent, the REC file is similar to the .img file used in the ANALYZE file format. The PAR file is an ASCII file that contains the text descriptions about the data, such as participant’s name, date of the scan, pulse sequence, image matrix, number of images, order of images, imaging parameters etc. This information is needed to open the REC file appropriately (for instance, you need to know how many rows and columns each image has in the REC file). The advantage of REC/PAR file format is that the data storage is efficient and the required storage space is relatively small. 2) DICOM file format. The DICOM file format is a more standard file format used widely in clinical radiology. Each DICOM file contains a tag section that describes the scan and a data section that stores the binary data. The DICOM files are typically stored in 2D format, so each slice is a file. Therefore, for fMRI and diffusion tensor imaging data, the number of files is often huge (>10,000 files). Since each file contains a copy of the description information, the information is stored redundantly and the resulting storage space is large.

The complex data (magnitude and phase) and the raw k-space data are also available if the research requires this information. However, please discuss with the AIRC staff BEFORE the experiment.

Interim Data Processing (on-the-fly)

There are three possible ways to conduct the interim data processing: 1) the researcher can conduct an online data processing on the scanner console during the experiment. The console has some basic data analysis tools such as drawing ROIs, looking at signal time-courses, adjusting window and
contrast of the images, performing image subtraction and average, conducting maximum intensity projection (MIP) etc. The advantage is that there is no need for file transfer or conversion. However, since the primary purpose of the console is MR scanning, online processing at the scanner console should be minimized. 2) The data can be transferred to a ViewForum workstation for data processing. The ViewForum workstation is made by Philips and has almost the identical interface as the scanner console (without the scanning part of course). The users can transfer the data to the ViewForum workstation and conduct analysis. Two ViewForum workstations are available at the AIRC: one in the 3T control room and one in the mock scanner suite. 3) The data can be transferred to the data server and/or PC for processing. The UNIX data server has the following software: MATLAB, SPM, AFNI, FSL, AIR, and ImageJ. Several PCs are also available in the 3T control room and in the mock scanner suite. The software installed is MATLAB, SPM, ImageJ, MRICro, and DicomWorks.

Available Computers
The AIRC has a UNIX server that has four terminals for the users to use. In addition, three PCs are available in the 3T control room and in the mock scanner suite.
Appendix A

Application for Visitor ID/Access Card

Last Name: _______________________________ First Name: _______________ M.I.___

Company Name & Address: ____________________________________________________________

Contact Phone Number(s): ____________________________________________________________

I assume full responsibility for safeguarding my access card, and agree not to allow any other
person to use my card. I understand that the access card remains the property of UT Southwestern Medical Center and may be confiscated at any time. I understand that failure to
do so may be the basis for disciplinary action by the University, and may result in revocation
of my card access privileges. I understand that I will be charged a fee of $50 to replace a lost or damaged card. Defective cards are replaced free of charge.

Signature: ________________________________________ Date:____________________

THIS SECTION TO BE COMPLETED BY THE AUTHORIZING DEPARTMENT:
I certify that the person named above is associated with the following UT Southwestern
Medical Center department/agency:_________________________________________________
__________________________________________________________________________
and has been authorized by said department to be issued a UT Southwestern Medical Center visitor identification badge. The person will require access to
the following specific rooms/areas and parking garages/lots (please specify any limitations by
times and/or days of the week):

The card will be needed through the following date:____________________________________
Name/Title of Department Liaison:________________________________________________________
Contact Phone Number/Extension:________________________________________________________
Signature of Department Director or Authorized Designee (please indicate):
________________________________________________________________________
Date:____________________

Any questions or concerns should be directed to the University Police
Department Access Control Division at 214.648.9700 or 214.648.2603

FOR OFFICE USE ONLY: Badge # __________________________ Date____________________
# Research Subject Atypical-Finding Report Form

Please complete form and submit to:  
[Jeannie.Baxter@utsouthwestern.edu](mailto:Jeannie.Baxter@utsouthwestern.edu)  
Or Fax 214-645-2744

<table>
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<th>AIRC #</th>
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<tbody>
<tr>
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<tr>
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<td>Subject ID:</td>
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<tr>
<td>Date of Finding:</td>
<td>Time of Finding:</td>
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<tr>
<td>Describe Atypical Finding:</td>
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<td>–reported by operator: ______________________________________</td>
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<td>Signature: ____________</td>
<td>Date Reported: _______________</td>
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AIRC operator Name and Contact Information:

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<tr>
<th>IRB STU#</th>
<th>Date and Time Reported to researchers:</th>
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<tr>
<td>Date and Time PI Received Written Notification:</td>
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Reviewed By:

_________________________  
AIRC Medical Director

Follow-Up Comments:
APPENDIX C

The University of Texas Southwestern Medical Center at Dallas
Advanced Imaging Research Center

MRI Machine Incident Report Form
(For reporting an injury, incident or any near incident of a projectile object.)
Please complete form and submit to:
Jeannie.Baxter@utsouthwestern.edu
Or Fax 214-645-2744

<table>
<thead>
<tr>
<th>Date of Incident</th>
<th>Time of Incident</th>
<th>Scanner or Machine Location:</th>
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Describe incident

Personnel Involved

Was anybody injured? If yes, please include name and extent of injury.

Was Zone IV screening performed on all personnel? Please explain

Corrective Actions:

<table>
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<tr>
<th>Supervisor Name</th>
<th>Phone Number</th>
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For office use only

Are all involved personnel properly trained?

Do all involved personnel have MRI screening form on file?
## AIRC Adverse Event Form
*(For reporting unanticipated or serious adverse events.)*

Please complete form and submit to: 
[Jeannie.Baxter@utsouthwestern.edu](mailto:Jeannie.Baxter@utsouthwestern.edu)  
Or Fax 214-645-2744

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<tr>
<th>Describe Event Details</th>
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<td>–reported by operator:</td>
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<tr>
<th>Signature:</th>
<th>Date Reported:</th>
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<th>Operator Name and Phone Number:</th>
<th>Researcher Present (include phone number):</th>
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<th>IRB:</th>
<th>IRB Adverse Event Reported: Yes: No:</th>
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<th>AIRC Medical Director</th>
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