

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

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## Research with Human Subjects at the AIRC

### 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 was founded 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.

## II. Research in the AIRC

#### New Research Grants

Before writing a new grant proposal for research utilizing the AIRC as a performance site, Investigators are advised to contact Ms. Jeannie Baxter for general guidance on AIRC policies and feasibility for new proposed research in the AIRC. Assistance for technical development of protocols is also available.

#### Reduced-Rate Funding for Pilot Projects (Internal Award or “IA” Award)

Partially subsidized scan time may be available for investigators gathering preliminary data for grant submissions. Investigators will share in the costs for this pilot data acquisition at a reduced rate below the regular hourly rate. Annually, subsidized funds will be set aside in a separate account and used to support pilot projects. Requests for subsidized pilot time are reviewed by an AIRC administrative committee lead by the AIRC Director. Subsidized pilot time will expire one year from approval. At the one-year expiration, a report detailing whether the award resulted in new grant funding or project publications is expected.

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### III. Protocol Review Committee (PRC)

#### 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.

#### Conduct of Business

Quorum: The PRC membership will consist of no more than fifteen members with multidisciplinary representation from UT Dallas, UT Southwestern, and UT Arlington. The presence of at least six members will constitute a quorum to start a meeting. If at any time membership should decrease to less than ten members, a majority will constitute a quorum.

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, and 5) environment, including collaborations and support from the home institution. 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

Jeannie Baxter, R.N., Advanced Imaging, UT Southwestern  
Ivan Dimitrov, Ph.D., Advanced Imaging, UT Southwestern  
Beverley Huet, M.S., Department of Clinical Sciences  
Elena Ivleva, M.D., Ph.D., Department of Psychiatry, UT Southwestern  
Joseph Maldjian, M.D., Department of Radiology and AIRC  
Craig Malloy, M.D. (Chair), AIRC, Departments of Internal Medicine & Radiology  
Ian Neeland, M.D., Department of Internal Medicine, UT Southwestern  
Michael Nelson, Ph.D., Department of Kinesiology, UT Arlington  
Karen Rodrigue, Ph.D., Center for Vital Longevity, UT Dallas  
Michael D. Rugg, Ph.D., Center for Vital Longevity, UT Dallas  
Bart Rypma, Ph.D., Center for Brain Health, UT Dallas; Psychiatry, 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. Binu Thomas 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
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
9. Provisions for Managing Adverse Reactions
10. Research Team and Collaborator Experience
11. References

#### Getting Started

1. Submit your project to the UT Southwestern IRB. Please include the AIRC as a performance site.
2. Submit an AIRC Application for Research with Human Subjects. Researchers may access the application via the AIRC website. AIRC Applications may be submitted while the IRB approval is pending. Please submit applications electronically to the PRC administrator [Jeannie.Baxter@utsouthwestern.edu](mailto: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 perform research procedures and work with participants. For more information or to register for safety training, please contact [Janet.Jerrow@utsouthwestern.edu](mailto:Janet.Jerrow@utsouthwestern.edu).
4. The PI along with research team members physically working in the AIRC are required to attend an implementation meeting prior to enrolling the first research participant. Contact Ms. Baxter to schedule.
5. Contact [Binu Thomas](#) for 3T pulse sequence setup, fMRI stimulus testing (if applicable), and other technical support prior to enrollment of your first research participant. Magnet time for setting up the protocol will be billed at the regular hourly rate.

#### Modifications to Approved AIRC Projects

Modifications to a project that require 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

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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](mailto: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. 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 provided by the AIRC is required for ALL badge access to restricted areas in the AIRC. Access will be granted based on requirements of the research.

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

Non-UTSW employed researchers must apply for a visitor badge using the Application for Visitor ID/ Access Card Form (Appendix A). To interact with research participants in the AIRC, all non-UTSW employed researchers must be employed by an affiliated UTSW entity (Veteran's Hospital, Texas Health Resources, Children's Medical Center and Parkland Hospital) or be covered under the applicable Memorandum of Understanding (MOU) with UT Arlington or UT Dallas.

### Support 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:

**3T Multi-Use Room (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)** primarily for support of 3T projects. All personal belongings of the research participant must be secured during an MR exam.

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**3TA Subroom (NE2.804)** is located within the 3TA suite and is specifically designated as an fMRI task training room. Blood draws and IV starts may be performed here.

**3TB Subroom (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.

**Exam Room (NE2.820)** is primarily reserved for use with the 7T scanner. Blood draws and IV starts may be performed here. An exam table is available for physical assessments.

**Mock Scanner (NE2.812)** 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.

**Dressing Room and Lockers (NE2.818)** is primarily available for procedures and the 7T scanner.

**Procedure Room (NE2.810)** is primarily for complex 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, describes common hazards and unique dangers associated with the MR environment and presents guidelines and recommendations to prevent accidents and injuries. This training is required for **all** research personnel who will access the MR facility in the course of their research. Online recertification is required annually and is facilitated by UTSW Environmental Health & Safety (EH&S).

Level 2 Training builds on Level 1 Training and provides the additional knowledge and expertise for independent operation of the MR system. Certified Operators will have access to all areas of the MR suite, and, when operating the scanner, are responsible for the safety of the research personnel, volunteers and visitors. See additional information "Operator Training."

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.

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### 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. Level 1 MR Safety Training must be completed before scheduling 7T Safety Training.

### Operator Training

Researchers desiring to operate a 3T or 7T scanner must complete Level 2 Training and demonstrate competency in proper positioning, in thermal and acoustic effects, and in the importance of preventing direct neurovascular stimulation. They must have knowledge and demonstrate the ability to respond appropriately to emergencies. 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. Any operator, with the exception of a licensed technologist, must have a second person in the control room to assist removal of a participant from the scanner in the event of an emergency.

Steps to become a certified operator:

1. The following criteria must be met to be eligible for training:
  - Request approval with a letter of recommendation from PI with purpose for training. Send to Binu Thomas (3T) or Ivan Dimitrov (7T).
  - Have intent to utilize training for at least two years in the AIRC.
  - Commit to complete training in a three-month period.
2. Once accepted as a trainee, successfully complete all requirements of Level 1 training and obtain CPR certification in Basic Life Support for Healthcare Professionals.
3. Become familiar with AIRC policies, MRI safety, power cycle of scanner and procedures for running phantom scans. Trainees may utilize research team members to acquire this knowledge or be trained in the basics from an MR technologist. If utilizing the MR technologist, an extra 15 minutes of time on the scanner must be scheduled to your research scan (and will be invoiced at the regular rate) to accommodate instruction time and the time to assess eligibility for check off.
4. The time expected for training by the technologist will vary based on the expertise and experience of the trainee. The technologist will confirm when a trainee is ready to be checked off as a certified operator.
5. Drs. Thomas or Dimitrov will provide the final check-off for operator certification. There will be no charge for this service as long as the scanner is not scheduled and it is done during a cancellation or otherwise unused, unscheduled time on the scanner. Alternatively, an extra 15 minutes may be added to a scheduled research scan. The extra 15 minutes will be invoiced.
6. Once checked off, schedule time with Ms. Baxter to review AIRC policies and sign commitment to adhere and follow all safety rules.
7. Due to demand of scanner time during peak usage, a moratorium may be implemented for new training in order to maximize time on the scanners for research studies.
8. Alternative training opportunities include vendor-sponsored training at their respective facilities.

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### 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 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 study population and give a recommendation to the PRC, ultimately, the PRC will determine case-by-case which participants may be scanned during off hours.

### MR Technologist Availability

MR Technologist availability will vary on each scanner depending on the demand. Generally, technologist coverage on the 3TB Philips system will extend to 8 p.m. starting November 1, 2018. The 3TA, 3TC, and 7T scanners will have operator assistance during regular work hours. An AIRC technologist is also available for 3TB scanning on Saturdays from 8 a.m. to 5 p.m. During this “tech-covered” time, it is 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. As noted elsewhere, the technologist may choose to terminate a study because of safety or other concerns.

AIRC scanners must be operated by an AIRC technologist or an AIRC Certified Operator. 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 an AIRC technologist is operating the system.

### Research Team Responsibilities

Research in the AIRC requires collaboration with the research team. The research team must provide personnel for all pre- and post-scan activities, which may include any of the following responsibilities:

1. Pre-screening for research and MRI eligibility

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2. Scheduling the scanner, support rooms and nursing assistance for IV starts and/or blood draws
3. Meeting the research participant at the AIRC and escorting to the MRI suite.
4. Preparing the research participant for the scan, which may include, but not limited to, consenting on the approved IRB protocol, screening the participant for MRI eligibility, providing instructions for locking up valuables, changing into scrubs, escorting to bathrooms prior to entering the MRI suite.
5. If there are any questions as to the participant's qualifications to undergo an MRI, this must be addressed with an MR technologist PRIOR to the study day. Participants who are disqualified after screening by the MR technologist on the study day (or within 48 hours) will result in a cancelled study and will be subject to the associated scanner fees.
6. Arranging any fMRI equipment setup prior to the scan. A technologist will assist, but the setup with the participant is primarily the research team's responsibility.
7. The research team member will be familiar with emergency procedures and will assist the MR technologist in removing a participant to a safe zone in the event of an emergency. Consequently, on arrival to Zone III, the research team member should remove all metal and store in the provided cubbies, so that assistance may be given immediately if needed.
8. Bring the required paperwork on arrival with the research participant. A scheduled scan will not commence without an approved IRB signed consent.
9. Responsible for arranging and confirming physician coverage for MRI contrast administration PRIOR to the day of the scan. Contrast will not be administered to a research participant without a licensed physician prepared to manage adverse events related to the contrast present in the NE building.

### Delays

To avoid delays, we strongly recommended that research participants arrive at the AIRC *at least* 30 minutes in advance of the scheduled scan time to allow for safety screening and preparation for the scan. Consider extra time for research participants with compromised mobility or for scans that require more complex setup prior to approaching the scanner. If the participant or the research team is running behind, the AIRC technologist will determine if there is flexibility in the schedule to complete a scan that starts late. A scan that starts late will be billed from the scheduled start time and will end when the research team has exited the scanner *and* the technologist has cleaned the room and completed data management (in 15-minute increments).

### Operator Requirements for 7T

Two individuals with Level 1 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 an irregular finding, the following procedures are applicable:

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

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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).
- Immediately report equipment damage or malfunction to Binu Thomas (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 AIRC Protocol Review Committee.

### 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. Quality Assurance required for specific investigator protocols will incur a fee for magnet use at the regular hourly rate.

### 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

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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 the AIRC 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 fMRI Audio-Visual Stimulation Technology**

A group of standard fMRI related equipment is available, which includes visual stimulation, response button boxes, audio stimulation, E-prime software, an eye-tracking system, and a mock scanner. The AIRC staff is responsible for maintaining and updating these devices.

### **New Devices in the Scanner Environment**

The investigator may have a project-specific device. It is crucial to discuss these devices with 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. Binu Thomas (3T) or Ivan Dimitrov (7T) must approve the use of any device.

## **VIII. Scheduling**

### **Online Scheduling System**

All research participants studied on the 3T and 7T scanners must be scheduled on the online scheduling system using the approved AIRC application number. The scheduling system resides on a University server and will allow the researcher to view, add, cancel and reschedule. Scheduling is accessible from any computer (within UT Southwestern or outside UT Southwestern) connected to the internet. A UT system username and password is required to log into the program.

Scheduling for approved projects is open up to 12 months in advance. A research participant’s name, birthdate, and phone number is required for scheduling. Holding random time in the hopes of finding a participant is not appropriate scheduling practice. Improper scheduling may result in suspended scanner use.

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### Administrative Holds

Administrative holds are scheduled by the PRC administration and may be used or released as needed. Generally, these are reserved for projects that require scheduling within a short amount of time due to study-specific inclusion criteria or for AIRC service needs.

### Conflicts and Priorities

AIRC operations flow according to the online scheduling system. Researchers may coordinate with each other to accommodate scheduling conflicts. It is the researcher's responsibility to communicate with each other for such arrangements. Any mutually agreed changes in the schedule must be reflected in the online calendar and/or recorded in the logbook.

### 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. To allow opportunity for all investigators, a ten hour maximum may be scheduled *per investigator* in a given week during peak usage. This number may be adjusted as needed. 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

The PI is financially responsible and will be invoiced once per month based on scheduled time in the online scheduling system. Failure to pay applicable charges may result in the suspension of the user account and of the use of the AIRC resources.

Billing and scheduling are based on quarter-hour increments with a minimum of 30 minutes. Billing begins and ends according to scheduled time provided that the scheduled time is sufficient for the scan and post scan activities. Failure to schedule enough time to accommodate all of the activities associated with your scan may result in incomplete data acquisition. If there is flexibility in the day's schedule, at the technologist's discretion, a scan *may* be allowed to run over the scheduled time. In this case, billing will extend beyond the scheduled time in 15-minute increments. For more accurate financial planning, please include the total time needed for each study subject when preparing grant proposal budgets.

Time spent by the operator preparing the scanner and console and time spent transferring and archiving data are billable activities and should be included in the scheduled time. AIRC staff generally will provide the PI with an estimate of the anticipated total scanning time. It is essential that the PI realistically consider the amount of time required for positioning in the scanner and all other setup activities. Similarly, the PI must include time for the participant to comfortably leave the scanner, clean up, data management such as transfer and archiving, and leave the room ready for the next study setup.

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Task setup on the fMRI computer that a) *does not involve use of the scanner* or scanner console and b) *is not scheduled on the calendar (blocking others from scanner use)* will not be considered billable time. Use of the fMRI computer is subject to needs of the scanner.

### Fee Schedule

3TA Philips and 3TC GE Scanners	\$525 per hour
3TA Philips Achieva	\$500 per hour
7T Philips Achieva	\$550 per hour
Pre-approved pilot time (Internal Award)	25% of cost per hour
Inhalation studies	Additional \$50
Gadolinium contrast	Per market per vial
Data processing (above baseline)	\$75 per hour
Research Coordinator	\$50 per hour
Registered Nurse	\$75 per hour
Blood Draws	\$25
IV Start for contrast	Included in scanner fee
Cancellation <48 hours	\$200 per hour of scheduled time
Aborted scans and "no-show"	\$200 per hour of scheduled time
Certified Operator check off	No charge if unscheduled and performed during scanner downtime

### Rate Increases

Periodic rate increases should be expected as direct costs in center operations increase over time. For grant proposal budgets, anticipate a 3% rate increase on April 1 annually.

### Cancellations

The cancellation policy is applicable during all operational hours Monday through Friday and during off hours with AIRC MR Technologist coverage. For purposes of the 48-hour cancellation, Saturday is considered a business day.

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

## 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" time. 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.

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### **Pregnancy**

Policies and practices with respect to imaging women of childbearing potential are determined by the IRB. Methods used to exclude pregnancy are the Principal Investigator's decision. Urine pregnancy tests are available in the AIRC 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 ferromagnetic 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 safety-trained MR research team member 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; 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: Research participants with metal implants will be considered on a case-by-case basis and must be approved by the PI and the AIRC Medical Director. Metal implants for consideration must be located in the part of the body that will be outside of the radio-frequency coil.

### **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.

## Research with Human Subjects at the AIRC

### 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 peripheral nerve stimulation (PNS) 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. 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.

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. All researchers are expected to respect the privacy of all 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.** Emergency medical interventions are performed outside of the restricted Zone III and Zone IV. The researcher will follow instructions from the MR Technologist to assist with calling for help and retrieving emergency medical supplies located in the 3TA Subroom.

## Research with Human Subjects at the AIRC

2. **Initiate CPR if indicated.** Stay with the participant.
3. **Contact emergency services.** The Ambulatory Services Rapid Response Team (RRT) is available Monday through Friday, 8 A.M. to 5 P.M. From a campus phone, dial 911 for the University Police and inform the dispatcher of the following:
  - 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 at 3TA. An AED is located in the hallway outside the 3TA control room. All researchers with AIRC badge access will be given access to 3TA.
5. **Contrast Reactions.** The designated study 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 the emergency responders 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. Current software version of

## Research with Human Subjects at the AIRC

both scanners is Release 5.1.7. 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. 3TA is also equipped with a broadband multi-nuclear spectroscopy and imaging RF amplifier covering 10-130MHz. A <sup>31</sup>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 imaging, 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

## Research with Human Subjects at the AIRC

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.

### **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. Alternative video and audio sources include CD player, DVD player, am/fm tuner, integrated through a system control center. Five 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 Linux data server (Dell Inc. PowerEdge R720) is available for processing and data storage. 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 or VPN and shibboleth from outside UTSW. 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 7 operating system. Some features are 2.8 GHz dual Intel Xeon processors, 3GB internal memory, 36GB system disk, 250GB 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.

## Research with Human Subjects at the AIRC

### 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

Offline data processing is available on one of our desktop PCs in the control room (software includes MATLAB, SPM, ImageJ, MRIcro, and DicomWorks).

## XIV. DATA MANAGEMENT AND ANALYSIS

### Data Backup by the AIRC

A Linux-based data server is maintained by UTSW Information Resources. 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. The data storage on the server is accessible by using VPN remote login using SSH or SFTP. Data may not be stored on the server for more than one year. After one year, the data will be administratively deleted from the server. Requests for data that has been removed will result in a fee for additional data processing. 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. All data will be transferred to the server in par/rec. format by the MR technologist at the time of the scan. Any other type of data format (e.g., dicom or nifty) should be requested at the time of the scan.

Access via SSH (Secure Shell):

Data transfer via SSH is available to UTSW users on campus with their own UTSW username and password. Virtual Private Network (VPN) connection is required for off-campus SSH-based data transfer.

To download or obtain more information regarding VPN, please follow the link below or call Information Resources at (214)648-7600.

<http://www.utsouthwestern.net/intranet/administration/information-resources/network/vpn/>

Users can use any SSH-based application (for example "WinSCP" or "putty") or use the "terminal" window with command line access available on any Unix/Linux operating system.

Please use the following parameters for SSH access:

Host name:	swlxaircapp.swmed.org
Port number:	22
User name:	UTSW username
Password:	UTSW password

After the SSH connection is established, please change directory to:  
/data/"PI's directory" to access data.

## Research with Human Subjects at the AIRC

### **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 a PC for processing.

### **Available Computers**

The AIRC has a Linux 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 \_\_\_\_\_



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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](mailto:Jeannie.Baxter@utsouthwestern.edu)

Or Fax 214-645-2744

Date of Incident	Time of Incident	Scanner or Machine Location:
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:		
Supervisor Name	Phone Number	

For office use only

Are all involved personnel properly trained?
Do all involved personnel have MRI screening form on file?

