

Research with Human Subjects at the AIRC

Policy and Procedure Guide

	Page
1. The AIRC	1
2. AIRC Protocol Description	3
3. Protocol Reviews And Modifications	3
4. Zones, Training and Safety	4
5. Scheduling And Billing	7
6. Operations	8
7. Medical Emergencies	10
8. Hardware	11
9. Software	13
10. Data Management and Analysis	14

1. The AIRC

Purpose

The Advanced Imaging Research Center (AIRC) provides a multidisciplinary environment for research in the imaging sciences. The early emphasis will be on advanced magnetic resonance research at 3T and 7T. Over the long-term, the 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.

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.

Getting Started

If you are a new user, please follow these steps:

- After reviewing this guide, to discuss the overall project, available equipment, and the resources necessary to carry out the project, please contact:
 - Dr. Hanzhang Lu (3T projects: Hanzhang.Lu@UTSouthwestern.edu)
 - Craig Malloy (7T projects: Craig.Malloy@UTSouthwestern.edu)

Research with Human Subjects at the AIRC

- Submit your project to the UT Southwestern IRB. This should be done before submitting your application to the AIRC.
- Submit your AIRC Application for Research with Human Subjects. Application forms may be obtained from the following URL: <http://www.utsouthwestern.edu/utsw/home/research/AIRC/index.html>. The AIRC submission may be done 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 Mrs. Baxter by email or by telephone at 214-645-2726.
- Assure that all personnel in the research team have suitable training for their work in the AIRC. This should include registering the PI and all research team members requiring access to the AIRC facility for AIRC MR Safety Training. Contact Janet.Jerrow@utsouthwestern.edu for more information.
- Once your AIRC application is approved, contact Mrs. Baxter to schedule an implementation meeting prior to enrollment of your first research subject.

User Fees

User fees are set by the AIRC Governing Board. The scheduling investigator is financially responsible and will be invoiced on a bi-weekly basis according to actual scan time. “No-show” slots or cancellations within 24 hours of the scheduled time will be charged a \$100 fee.

The current scan rate for the 3T scanner is \$500 per hour. The current scan 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. If a subject is found to be claustrophobic and cannot participate in the study after the MR technologist has attempted to position the subject, the investigator will be charged based on the actual time used or 30 minutes, whichever is greater. Investigators are encouraged to use the mock scanner, at no additional charge, to test whether their subjects are claustrophobic in advance of the scheduled appointment time.

Further details of scheduling and billing can be located in Section 5 of this guide.

Pilot Experiments

Scan times may be available for gathering preliminary data for grant applications. If the PI is 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.

Intellectual Property

If a project does not involve contribution by UT Southwestern faculty to the development of intellectual property, UT Southwestern will not claim rights to such intellectual property.

2. AIRC PROTOCOL DESCRIPTION

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 information:

1. Title
2. Sponsor
3. UTSW Account Number
4. IRB File Number(s)
5. Principal Investigator
6. Research Coordinator
7. Members of the Research Team
8. Experimental Conditions
9. Purpose of the Study or Hypothesis to be Tested
10. Background and Results of Previous Related Research
11. Description of Procedures to be used in the AIRC
12. Subject Selection and Number of Scans
13. Duration of the Project³
14. Provisions for Managing Adverse Reactions
15. Research Team Experience
16. Reference Citations

3. PROTOCOL REVIEWS

Relation of the AIRC Protocol Review Committee (PRC) to the IRB at UT Southwestern

The UT Southwestern IRB must review and approve every project involving human subjects at the AIRC. It is probably worth stating that the IRB review is much more comprehensive than the AIRC review. The AIRC process focuses 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 AIRC 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 AIRC.

The Review

The following criteria will be considered in the review: 1) significance, 2) approach including feasibility and technical resources required for the project (such as 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 feasibility. After review, there will be one of two responses: 1) approved or approved with stipulations, or 2) deferred with questions. If it is deferred, the response will include the Committee's concerns. If it is

Research with Human Subjects at the AIRC

approved with stipulations, approval will require a response to Mrs. Baxter addressing the stipulations.

Modifications to Approved AIRC Protocols

Any modifications to a protocol that require a change on the IRB consent form, changes to the description of procedures used in the AIRC, or changes to research personnel working in the AIRC, must be approved by the PRC. A modification form can be downloaded from the AIRC website and submitted electronically to Mrs. Jeannie Baxter. Depending on the nature of the change, the modification will receive an administrative approval or an evaluation from the Committee.

Committee Members

Jeannie Baxter, R.N., AIRC

Ivan Dimitrov, Ph.D., AIRC

John Hart, M.D., Center for Brain Health, University of Texas at Dallas

Beverly 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

4. ZONES, TRAINING AND SAFETY

The MR area of the AIRC is divided into 4 zones. This classification, suggested by the American College of Radiology, is commonly used in discussions about MR safety and for this reason is described 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 strictly controlled Zones III and IV. Subjects are greeted in the waiting room and escorted into Zone II, which includes the connecting hallways, interview rooms, and the mock MRI scanner area. Subjects must be escorted in Zone 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 means the magnet room itself. Only personnel trained at Level 2 (see below) are allowed into Zone IV.

Training

The experience and training of the various members of the research teams will be variable. Since the highest priority is safety for the research subject, the AIRC requires training in safety for the subject, for other individuals in the vicinity, and in proper operation of the system. The AIRC 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.

All members of the research team who require access to the AIRC are required to take MR safety training provided by the AIRC. Level 1 provides the basics of MR safety

Research with Human Subjects at the AIRC

and technology. It 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. Typically, these individuals will be students or assistants working directly with the operator or the PI or other members of the research team. Level 2 pertains to staff handling phantoms or working with human subjects in the magnet room.

The intent of the safety training is not to achieve expertise as an MR technologist. The operator is the “captain of the ship” and will direct all activities in the magnet room. However, any person working in the magnet room should be aware of proper patient positioning, the importance of thermal and acoustic safety and the importance of preventing direct neurovascular stimulation.

Levels 1 and 2 are provided in a combined 30-minute presentation followed by a brief quiz. Additionally, an on-line annual renewal course is required in order to maintain badge access to AIRC facilities.

People with Prior Training on Other Systems

Different MR vendors typically have different user interface, terminology and functionalities. Even the scanners from the same vendor may be running on different versions of software, clinical science keys and R.F. and gradient coil configurations. Therefore, researchers with prior training on other systems will still need to pass the specified training at the AIRC.

Confidentiality and Protection of Health Information

No names, social security numbers, research study numbers, etc., will be entered into the scanner console. The operator is responsible for entering into the logbook the consecutively numbered exam identifier, the AIRC protocol number and the name of the PI. It is the responsibility of the PI and/or designee to make note of the exam identifier.

Safe Research Environment

The research team and the MR operator are together responsible for safe operation of the instrument. The designated instrument operator is in charge. During a study, the operator will consult with the PI and members of the research team, as needed. (In some instances, the operator and the PI is the same person.) If the operator feels the study is in any way unsafe or inappropriate, the study will be cancelled. The PRC or the PRC Chair has the discretion to rescind approval of any research protocol for violation of AIRC policies and procedures. Of course, 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.

Screening Procedures and Metal Hazards

A research team member trained at Level 2 must accompany every research subject. All research subjects (or parent or guardian, as appropriate) is required to sign a “Magnetic Resonance Procedure Screening Form for Subjects” prior to any procedure. A signed copy of this screening form and the current, correctly dated IRB Informed Consent Form and HIPAA Authorization is required for AIRC records. Place all forms in the designated area in the control room.

Research with Human Subjects at the AIRC

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 non-magnetic and either MR safe or MR compatible. Fire extinguishers, oxygen tanks, and aneurysm clips 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-magnetic and MR compatible. Never assume MR compatibility.

Any individual undergoing a scan must remove all metallic personal belongings and devices on or in them. 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. It is advisable to require research subjects to wear a gown during MRI procedures.

Some drug-delivery patches contain metallic foil. If, in consultation with the prescribing physician, it is determined safe to remove the patch, a designated staff member is responsible to replace or reposition the patch. Otherwise, no scan may proceed on a subject with any drug-delivery patch or pad.

Acoustic Noise

All subjects must use hearing protection during any imaging in the MR scanners.

General Precautions During a Study

The instrument will not allow scans to run above FDA specified limits. However, the operator must accurately indicate the subject's age, weight and gender before scanning since these parameters are included in limit computations. Some protocols have the potential for inducing peripheral nerve stimulation during the scan. The usual precautions should be followed during all scans. For example, instruct the subject to inform the operator if they experience discomfort or pain. Instruct the subject not to cross arms or legs in the MR scanner. Be in constant contact with the subject. Stop the scan if the subject complains of severe discomfort or pain. Report any incident involving discomfort or pain to either Dr. Lu (3T) or Dr. Malloy (7T).

Contrast Agents

Studies requiring contrast-enhanced MRI must have approval of AIRC PRC and UTSW IRB through their respective review processes. MR technologists and registered nurses who have been trained to initiate and attend peripheral IV lines may administer FDA-approved gadolinium-based MR contrast agents. All contrast agents must be administered as directed by a licensed physician. The physician must be immediately available inside the Clements Building to intervene should a subject experience contrast agent-related complications during an MR scan.

5. SCHEDULING AND BILLING

All studies with human subjects on the 3T and 7T scanner must be scheduled on the online scheduling system, a computer program running on a University server. The scheduling system will allow the researchers to view, add, cancel and change the scanner schedule. The program is accessible from any computer (within UT Southwestern or outside UT Southwestern) connected to the internet. A user name and password is required to log into the program. Each principal investigator will be assigned a user name and password, and it is the principal investigator's decision to decide whether to share those with other researchers in his/her group (e.g. post-docs, students). One principal investigator may have more than one project at the AIRC, but only one user name will be assigned with the choice of different protocol numbers.

Scheduling a Scan

The online scheduling system address is: <https://swsuairc.swmed.edu>. Scheduling for approved projects is on a first-come, first-served basis. Scanner time slots should be scheduled in 15-minute increments (30-minute minimum). Please add an additional 15 minutes to your scan time to allow for positioning and removal of the volunteer from the scanner bed. If your scan takes longer than expected, the technologist will decide, based on the day's schedule, whether additional time is available. You will be billed according to actual scan time used.

It is very important that you ask your subject to arrive at the AIRC at least 30 minutes in advance of the scheduled scan to allow time for screening and preparation for the scan. Slots may be scheduled from the present time to 12 months in the future. An approved AIRC protocol number is to be specified when scheduling a slot.

Cancellations

Cancellation of a slot should be done at least 24 hours before the start of the scheduled scan. There are no limits on the number of cancellations the researcher can request, but the AIRC staff will check the scheduling activities on a regular basis to avoid any abuse of the scheduling system (e.g. reserve many slots, and then cancel most of them before the scan). If the study is scheduled, but the time is not used or cancelled appropriately, a \$100 fee will apply. However, if another investigator can use the slot and is willing to pay for the time, your account will not be charged.

Investigators should be prepared with backup plans in the event that a subject does not arrive as planned. For example, some studies require volunteers to serve as normal controls. These subjects could be scheduled as backup. Investigators could also be aware of other studies that may have an urgent need for magnet time.

Billing

The AIRC will bill the investigator based on the online scheduling system and the logbook on a bi-weekly basis. It is the investigator's responsibility to pay the charges in a timely manner. Failure to pay the previous charges may result in the suspension of the user account and the use of the AIRC facilities.

Scheduling Conflicts and Priorities

The AIRC facilities operate according to the schedule, set as described above. Individual investigators may coordinate with each other to accommodate special situations of scan scheduling. It is the investigator's responsibility to communicate with each other for such arrangements. Any mutually agreed changes in the schedule must be communicated to the AIRC for proper billing.

Mock Scanner

The mock scanner is available for training subjects. It is scheduled through the online system and there is no additional charge for its use.

6. OPERATIONS

Instrument Availability

The 3T instrument is available for operation 12 hours a day (8 A.M. to 8 P.M.), Monday - Saturday, and on Sunday from 1 P.M. to 7 P.M. The 7T instrument is available for human subjects only during ordinary work hours. Ordinary working hours are considered to be Monday – 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 subjects at the AIRC, the principal investigator should consider that the AIRC is not physically connected to any emergency care facility. Emergencies in the Clements 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. Although the PI may make an assessment of their subject population and give a recommendation to the PRC, ultimately, the PRC will determine, case-by-case, which subjects may be scanned during off hours.

In general, any study involving a subject 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.

Technologist Assistance 3T

An AIRC MR technologist will be available for MR scanning from 8 A.M. to noon and 1 P.M. to 6:30 P.M. on ordinary University workdays. During this "tech-covered" time, it will be the MR technologist's responsibility to perform or supervise the performance of the MR scans. The technologist may, at his or her sole discretion, request physician supervision during any scan.

For the time slots without tech coverage, it is the investigator's responsibility to provide a qualified operator approved by Dr. Hanzhang Lu. Approved operators must provide documentation of Basic Life Support certification.

In general, the operator and at least one other person must be in the control room during off-hour scans, regardless of the subject's health status. The only exception is if Dr. Lu or Rani Varghese is operating the system. Other exceptions to this rule may be requested and must be approved by both the PRC and Dr. Lu.

Technologist Requirements for 7T

Two individuals with Level 2 training must be present in the 7T control room at all times when a human subject is being studied in the scanner. Both persons are also required to have specific training related to 7T emergency procedures. At least one person must have a minimum of Basic Life Support training. An AIRC research nurse or the 7T technologist will screen all subjects. The magnet operator must review the MR screening form prior to the scan.

Every human subject will have a blood pressure and heart rate check pre and post scan by an AIRC research nurse or other medical personnel present for the study.

Abnormal Findings in Research Data

Only research protocols are carried out in the AIRC. If an investigator should discover an abnormality during a research scan, the AIRC recommends the following procedure:

1. Inform the research subject of the questionable finding.
2. Instruct the subject to follow up with a physician regarding the matter.

Subjects should be made aware that imaging during a research protocol is not the same as imaging done for medical diagnostic purposes. Upon request, we will recommend language to add to your consent form.

Scanner Malfunction

During regular hours, immediately report any problems related to scanner malfunctions to the MR technologist, Dr. Lu (3T) or Dr. Malloy (7T).

Reporting Incidents

It is the responsibility of the Operator to notify Dr. Lu or Dr. Malloy immediately of any incident related to safety of subjects or staff, possible equipment damage or malfunction, or a circumstance in which a protocol was not followed as approved by the PRC or IRB.

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 the AIRC staff.

Available Protocols

Standard MRI protocols will be available on the scanner and saved on a protocol folder named "AIRC protocols". The researchers are welcome to use them as needed, but please do not change these protocols. The researchers are also welcome to create an individual folder under the "User defined" directory, in which they can save their own optimized protocols. Typically, at the beginning of a project, the researchers will copy certain standard protocols and make customized modifications. These optimized

Research with Human Subjects at the AIRC

protocols will be saved in their own folder for future use. The detailed protocols are included in the “Available sequence” section and can be found on the scanner console.

New Protocols or 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 the AIRC staff or the 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 obtaining a Philips pulse sequence from another Philips site does not necessarily make the implementation easier because different sites may have different software versions, hard configurations, coil availability etc. Very often, the pulse sequence would need to be re-implemented even if it is operational on another Philips system. Overall, consultation with the AIRC staff is highly recommended for any protocol transfer.

Integrating Stimulation Protocols with Scanning

A group of standard fMRI related equipment is available at the AIRC, including visual stimulation, audio stimulation, response button boxes, E-prime software, eye-tracking system and a mock scanner. The AIRC staff is responsible for maintaining and updating these devices. If investigators are interested in using these devices, please contact the AIRC staff for a training session. All researchers from one group or laboratory should be trained in one 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 subject 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.

7. MEDICAL EMERGENCIES

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

Research with Human Subjects at the AIRC

1) Remove the subject and scanner bed from the magnet room.

The Philips scanner bed is detachable. Remove the subject and scanner bed 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) Call for assistance and initiate CPR if indicated.

The individual noting the medical emergency will call for assistance. The first qualified person on the scene will initiate CPR, if indicated.

3) Contact emergency services.

The Ambulatory Services Emergency Response Team (ERT) is available Monday-Friday, 8 A.M. to 5 P.M.). From a campus phone, dial the University Police at 911, and inform the dispatcher as follows:

- The nature of the emergency: This could be cardiac arrest, seizure, severe drug reaction, respiratory arrest, etc.
- The location: Tell the dispatcher your location is Clements 3T or Clements 7T.
- Activate the ERT: Tell the dispatcher to activate the ERT. The dispatcher will activate the ERT pagers. 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 dispatch at 911. Give your location (Clements Advanced Imaging), state the nature of the emergency, and request that they call Emergency Medical Services (EMS). Do not use a cell phone. The University Police know the campus and can quickly direct EMS to the subject.

4) Contact the Relevant Physician, If Appropriate.

The subject's physician, if available and applicable, should assume responsibility for managing the emergency.

5) Other Responsibilities of Research Personnel

Alert the Rogers clinical MRI staff of the code and the location of the subject. Post one person at the entrance to the Rogers MRI to direct the response team into and through the clinic to the code. Page the AIRC Medical Director to request assistance with the code. Go to and remain at the scene of the emergency; be ready to help until enough ERT members arrive.

8. HARDWARE

The 3T Scanner

The Achieva 3.0T (Philips Medical Systems) is equipped with 16 independent R.F. receiver channels (each channel 3MHz bandwidth) and a Quasar dual gradient system capable of an axis (x, y and z) 80mT/m peak and 200mT/m/ms slew rate. The gradient system can be used to generate any type of gradient waveform at 100% duty cycle. Special acoustic noise reduction is included in the system with a reduction rate of 30dB. The RF power amplifier is capable of generate a maximum power of 25kW. The image

Research with Human Subjects at the AIRC

reconstruction computer is equipped with 4GB reconstruction memory and can reconstruct 1200 images per second. Patient bore diameter is 60cm (23.6 inch) and length is 60cm. The table can manage subjects weighing up to 250kg (550 lbs).

Available Sequences

The available sequences include gradient-echo, spin-echo, echo-planar-imaging (EPI) for fMRI, diffusion imaging including on-line 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, 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, 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, 16-channel SENSE receive-only neurovascular coil.

Physiological and Visual Monitoring

The facility provides a 42-inch plasma TV to monitor the subject, 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 subject-operator communications, music entertainment for the subject, peripheral pulse, respiratory pulse, vector ECG, display of these physiological signals on the operator's console monitor, 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), 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 should be supplied via the penetration waveguide from outside the magnet room.

Contrast Agents

FDA-approved MR contrast agent may be administered to the subject by an authorized staff by either manual injection or using a power injector. A power injector and the accessories will be supplied by the AIRC. However, it is the investigator's responsibility to find the authorized staff for I.V. preparation and the contrast agent

Research with Human Subjects at the AIRC

injection. It is also the investigator's responsibility to determine the appropriate dosage, injection rate, etc.

Intravenous Lines

The I.V. line has to be prepared by a physician or physician assistant or nurse. A nurse or an MR technologist is allowed to prepare the I.V. line only with a designated physician physically in the Clements Building.

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 subject 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 data storage and processing. 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 the investigators 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.

Non-Ambulatory Subjects

The AIRC is not equipped to handle non-ambulatory subjects. Further notifications will be posted when this situation has changed.

9. 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 subject, 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 scannings, which includes NeuroPlus Package, BodyPlus Package, BreastPlus Package, OrthoPlus Package, CardiacPlus Package, AngioPlus Package, OncoPlus Package and

Research with Human Subjects at the AIRC

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 is 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).

10. DATA MANAGEMENT AND ANALYSIS

Data Backup by the AIRC

The AIRC has a UNIX-based data server that 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. The investigators 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 MOD disk, a DVD or a USB memory via a built-in drive. 2) The data can be transferred to the data server first, then, they can be burned to a CD/DVD. 3) The data on the data server can be remotely downloaded via a network connection (e.g. SFTP).

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

Research with Human Subjects at the AIRC

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 subject 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 require 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 stores 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 for MR scanning, online processing 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, ImageJ. Several PCs are also available in the 3T control room and in the mock scanner suite. The software installed is MATLAB, SPM, ImageJ, MRlcro, and DicomWorks.

Computers Available

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.