

University of Arkansas for Medical Sciences Brain Imaging Research Center



MRI Policies and Procedures Manual Version 4.3

These Policies and Procedures represent a living document that may be changed or amended as needed by the MRI Operator. All members of the BIRC as well as any other collaborating staff will familiarize themselves with these policies and procedures as frequently as necessary to ensure a thorough working knowledge of their contents.

Definitions

Abbreviations/Terms

5-Gauss Line: boundary past which the magnetic field surpasses 5-Gauss, past which ferromagnetic objects will interact with the magnetic field. This line will be marked in the MRI Scanner Area at all times.

BIRC: Brain Imaging Research Center, used in reference to both the location and the entity collectively

BIRC Research Staff: members of the Brain Imaging Research Center, may include BIRC faculty, staff, and students

Collaborating Staff: any non-BIRC faculty or staff member who interact with BIRC Research Staff or MRI Operator to utilize the MRI Scanner for their own non-BIRC research study or other faculty members who contribute to BIRC research studies.

MRI: Magnetic Resonance Imaging, used to reference the machine itself

MRI Control Room: area containing the MRI Console Computer, EPIC Computer, SAFESCAN, and other safety equipment. For diagram of this area, see Appendix 1

MRI Operator: person selected to operate the MRI Scanner and related equipment

MRI Scanner Area: area containing the MRI Scanner and equipment needed for scanning. For diagram of this area, see Appendix 1

MRI Simulator: machine that recreates the environment inside the MRI Scanner itself. It consists of a bed that moves into and out of the bore, a plastic head coil with mirror, screen used to do the tasks, speakers that play audio recordings of scanner sounds, and button boxes used to make motor responses when required.

Scanning and Screening Materials

The Brain Imaging Research Center uses the following electronic equipment when performing scanning procedures:

- Philips Achieva 3Tesla X-series MRI
- Philips SENSE 8-channel head coil
- Philips 32-channel head coil

- Mednovus™ SAFESCAN® Target Scanner™ handheld ferromagnetic detector
- Psychology Software Tools, Inc. (PST) MRI Simulator (if needed)
- EPIC (Experiment Presentation and Interface Computer)

Duties and Responsibilities

1. MRI Operator: The MRI Operator is responsible for the MRI Scanner itself and ensuring its proper functioning. The MRI Operator is responsible for the safety of any participants, BIRC Research Staff members, or Collaborating Staff members. As such, the ultimate decision on who may be scanned falls to the MRI Operator. The MRI Operator may dismiss anyone from the MRI Scanner Area or MRI Control Room at any time, participant or staff.

MRI Operator Duties

Scanner operation
 Scanner maintenance
 Periodic Image Quality Testing (PIQT)
 Participant screening using MRI Safety Screening Form and SAFESCAN®
 Obtaining and evaluating participant medical records if necessary
 Filing medical records
 Initial MRI Safety Training for new BIRC Research Staff or Collaborating Staff
 Design and implementation of exam-cards for new studies
 Transfer of data for all studies
 Facilities inventory and restocking of necessary supplies
 Any other duties deemed necessary by the BIRC Director

MRI Operator Responsibilities

Safety of participants and staff
 Thorough screening of participants
 Operating the MRI Scanner
 Set up and break down of MRI Scanner equipment
 Acclimation of participants in the MRI Simulator
 Maintaining equipment in good working order
 Maintaining sufficient stock of scanner supplies
 Maintaining a safe scanning environment
 Maintaining the BIRC Scanner Schedule calendar
 Maintaining MRI associated files, including participant medical records and Confidentiality Agreements
 Updating BIRC MRI Policies and Procedures as needed

2. BIRC Research Staff: Designated members of the BIRC Research Staff are responsible for maintaining participant flow through the scanner. This includes assisting the MRI Operator in screening and acclimating participants to the scanner and tasks. For BIRC Research Staff Members who obtain Informed Consent for participants in BIRC studies,

it is important that these individuals are able to ensure that all participants understand the MRI procedures that will be administered for that study as well as risks associated with the MRI.

BIRC Research Staff Duties

Maintaining efficient flow of participants
Practicing tasks with participants prior to scanning
Acquiring and testing urine sample if required
Assisting MRI Operator in acclimating participants in the MRI Simulator
Other duties as needed by the MRI Operator and/or BIRC Director

BIRC Research Staff Responsibilities

Ensuring participants understand tasks
Ensuring MRI Operator has all information necessary to evaluate safety of participants
Screening participants before and during their participation in BIRC research studies
Maintain a thorough working knowledge of BIRC MRI Policies and Procedures
Maintaining current Safety Training after initial safety training is complete

3. Collaborating Staff: Collaborating Staff members are responsible for the management of participants in non-BIRC studies. Collaborating staff on non-BIRC studies should have a thorough working knowledge of the policies and procedures of the BIRC MRI. As these staff members are obtaining Informed Consent for MRI procedures, it is crucial that these individuals are able to ensure participant understanding. Also, for non-BIRC studies, it is important that these individuals are able to ensure that all participants understand the MRI procedures that will be administered for that study as well as risks associated with the MRI.

Collaborating Staff Duties

Escorting participants to and from the BIRC MRI
Initial screening process prior to MRI procedures
Providing BIRC Research Staff and the MRI Operator with accurate study information

Collaborating Staff Responsibilities

Ensuring that all scanning procedures for non-BIRC studies are compliant with the currently approved protocol and consent
Screening participants before and during their participation in non-BIRC research studies to ensure participant safety
Ensuring MRI Operator has all information necessary to evaluate safety of participants
Maintain a thorough working knowledge of BIRC MRI Policies and Procedures
Maintaining current Safety Training after initial safety training is complete

Procedures

Screening Procedures

The Brain Imaging Research Center uses the following screening procedures to be implemented each time a participant comes to the BIRC for a scan prior to every scanning session. Not all of these procedures are documented as scanning will not be completed if any of the following procedures are not followed.

1. Urine sample will be collected IF one or both of the following conditions are met:
 - ❖ Participant is a female. All females of childbearing potential are required to provide a urine sample to test for pregnancy, including participants in collaborating research studies. A urine serum pregnancy test will be used. A positive pregnancy test represents exclusionary criteria as stated in all BIRC protocols and consents.
 - ❖ The protocol under which the participant is being scanned requires a urine-based drug test. The results of the drug test may or may not represent exclusionary criteria, depending on the protocol under which the participant is being scanned.
 - ❖ If a participant does not provide a urine sample under these conditions, they will not be allowed to participate in the MRI.

2. Completion of the MRI Safety Screening Form by MRI Operator and participant being scanned. This is required for collaborating research studies as well.
 - ❖ Each study will work from the currently approved screening form for that study.
 - ❖ The MRI Safety Screening Form **MUST** be completed by the MRI Operator in a manner resembling an interview. The MRI Operator will complete the form based on the responses of the participant. A member of BIRC Research Staff may complete this form with the participant under the MRI Operator's authority.
 - ❖ In the case of an adolescent participant, the form will be completed by the parent or guardian of the adolescent being scanned. Both the parent/guardian and the adolescent participant will sign the form upon completion.
 - ❖ If a participant indicates they have internal metal, the MRI Operator will evaluate their safety. If necessary, medical records will be obtained in accordance with BIRC MRI Policy 9. The MRI Operator may suspend or cancel a scan if more information is required to make a decision on the safety of the participant.
 - ❖ If a participant indicates the presence of tattoos and/or permanent cosmetics, they will not be automatically excluded. Rather, an Investigator on the project will be consulted and, in conjunction with the MRI Operator, reach a decision regarding the safety of the participant in the scanner. The Investigator will initial the Safety

Screening form as proof of his/her consent to allow the participant to be scanned. MRI Operators and BIRC Research Staff will monitor the participant during their scan and initial if no problems presented.

- ❖ If a participant has two scans in one day, they will only be required to complete the MRI Safety Screening Form one time.
- ❖ Failure to comply with this policy will result in the participant being removed from the study.

3. Additional screening with the SAFESCAN® ferro-magnetic detector.

- ❖ Participants will first be asked to remove everything from their pockets, all jewelry, and any other objects that may contain metal. Failure to comply with this policy will result in the participant being removed from the study. Participants will then be scanned using the SAFESCAN® ferro-magnetic detector.
- ❖ The scanner will indicate any large ferro-magnetic objects on the participant. The participant will be required to remove any objects the detector detects. Failure to comply with this policy will result in the participant being removed from the study.

Pre-scanning Procedures

The Brain Imaging Research Center uses the following procedures to acclimate and orient the participants to the scanning environment and tasks to be completed in the scanner. These procedures may be used prior to each scan a participant receives at the BIRC. The following procedures, if required, will be performed by either the MRI Operator or BIRC Research Staff.

1. Acclimation in the MRI Simulator will occur if any of the following conditions are met:
 - ❖ Participant has never been scanned and has some anxiety concerning scanning procedures.
 - ❖ Participant has some claustrophobic tendencies.
 - ❖ BIRC Research Staff feel the participant or the study would benefit from acclimation in the MRI Simulator.
 - ❖ The PI of the study requests a participant be acclimated in the MRI Simulator.

If a participant is still feeling anxious or claustrophobic following the session in the MRI Simulator, the BIRC reserves the right to exclude that participant from the study. The BIRC will maintain documentation on the use of the MRI Simulator, specifically who was acclimated in the MRI Simulator and why. The documentation will be completed by the MRI Operator or BIRC Research Staff. Documentation of acclimation in the MRI Simulator will be included on each participant's MRI Safety Screening Form. The

documentation on the MRI Safety Screening Form will be limited to whether or not the participant was acclimated in the MRI Simulator.

2. Participant will practice the tasks they will be required to do in the scanner.
 - ❖ Practice may occur in the MRI Simulator or at the EPIC computer in the console control room.
 - ❖ For tasks whose instructions are fairly simple, no practice may be necessary.
 - ❖ Some tasks, due to their design, necessitate the participant learning the task while in the scanner. For these tasks, instruction will be given to the participant prior to the scan concerning how to maneuver through the task itself.
 - ❖ The BIRC will handle participant practice sessions on a case-by-case basis.
3. For participants with poor vision, MRI-compatible glasses will be available.
 - ❖ The set consists of plastic frames and interchangeable lenses. The MRI Operator or a member of BIRC Research Staff will work with the participant to establish the correct set of lenses for optimum vision correction. At no point will the participant handle the lenses or change them out themselves.

Scanning Procedures

The Brain Imaging Research Center uses the following procedures while scanning participants. Unless otherwise noted, all the following procedures will be performed by the MRI Operator. These procedures are also not documented, as failure to comply will result in the participant being removed from the study. For Policies concerning scanning procedures, please see BIRC MRI Policies 9 through 16.

1. Scanner room and console computer will be prepared for each scan prior to the start of each scan. This includes preparing all coils and other equipment needed.
2. Each participant will be escorted into the scanner room and prepared for the scanning session.
 - ❖ Each participant will be given a Vitamin E liquid gel pill to be taped to the left temple to serve as a marker during analysis.
 - ❖ Each participant will be given a set of ear plugs to wear during the scan.
 - ❖ Each participant will be given a set of headphones to wear during the scan.
 - ❖ If the scan consists of a task in which responses are required, each participant will hold the MRI-compatible button box to make responses during the scan.
 - ❖ Some protocols require physiological measurements taken on participants during the scans. For scans performed under those protocols, each participant will wear a

chest pad to monitor breathing and a finger pad to monitor heart rate. The chest pad will be held in place with a strip of padding designed for the chest pad. The finger monitor will be placed on the non-dominant hand, and held in place with a piece of medical tape.

- ❖ Each participant will be given a call button to use to signal the MRI Operator if they become too anxious or uncomfortable to finish the scan. Participants will be instructed on how and when to use it prior to each scan. Additionally, the MRI Operator will verify that the call button is functioning properly after loading the participant into the scanner.

- ❖ Any padding and cushions may be used to make the participant more comfortable.

At no point should any of the above items be removed from the participant.

At no point should extra padding or blankets impair the function of any of the above items.

3. Head coil will be fitted and proper alignment set for each participant.

- ❖ Participants may be required to reposition themselves in the head rest to improve alignment for the scanning procedures.
- ❖ The head coil will be moved into place and foam cushions inserted on either side of the participant's head to minimize head movement. The head coil will be locked into place.
- ❖ Correct alignment will be obtained using a machine-mounted laser light. Participants will close their eyes to prevent any damage to the eye. As each person is different, alignment will be set by the MRI Operator to produce the best quality images.
- ❖ Once alignment is set, the participant will be moved into place within the bore of the machine and the first scan will begin.

4. Positional scans will be performed.

- ❖ Two scans will be performed prior to any functional imaging. These are used to ensure proper alignment in the scanner and verify the participant does not have any internal metal in the head or neck region. These scans are required for every scanning session.

5. Functional scans will be performed.

- ❖ These scans vary with each protocol and are programmed to correspond with a particular task the participant will be instructed to perform.

6. Anatomical scan(s) will be performed.

- ❖ These may be done before or after the functional imaging takes place.
- ❖ These are required for each scanning session to allow for data analysis.

7. Participant will be removed from the scanner.
 - ❖ Participant will be removed from the scanner and escorted from the scanner area.
 - ❖ All equipment used for each participant will be removed after each scanning session is completed and escorted from the scanner room.

Post-scanning Procedures

The Brain Imaging Research Center uses the following procedures after the completion of a scanning session. Unless otherwise noted, all procedures will be completed by the MRI Operator.

1. Following each participant scan, the scanner area will be cleaned.
 - ❖ If another participant is scheduled to be scanned that day, linens will be removed and replaced including cloth headphone covers. All surfaces that came in contact with the participant will be cleaned with anti-bacterial, anti-viral wipes. While cleaning, staff will wear gloves to prevent cross-contamination of surfaces. Gloves will be disposed of after cleaning. This may include, but is not limited to, head coils, button boxes, call button, etc. Once all surfaces are cleaned, equipment will be reset in preparation for the next scanning session.
 - ❖ If no other participant is scheduled that day, all equipment is to be cleaned as described above and stored in the correct location for that piece of equipment. All linens used that day will be disposed of in hampers provided by the hospital. The MRI Operator will ensure that all equipment and paper documents are put away or disposed of.
2. Any data collected that day will be transferred to an Export folder on the MRI console computer.
 - ❖ This folder can be accessed by other BIRC Research Staff by using the username and password assigned to the console computer.
 - ❖ BIRC Research Staff will move the data to a secure server used by the BIRC for long-term storage. All data acquired during scanning will be identified with a study-specific code rather than names or social security numbers.
 - ❖ Data will also be transferred to back-up storage on external hard-drives. These hard drives are encrypted with True-Crypt encryption software.
 - ❖ All aspects of the data transfer will be documented.
 - ❖ If no other scans are scheduled for that day, all computers will be shut down or logged off, including the EPIC and MRI Console Computer.

Policies

The magnetic field of the scanner is always on and dangerous. Ferromagnetic objects, if introduced to the magnetic field beyond the 5-Gauss line may become projectiles, potentially injuring staff and participants. The BIRC maintains a zero-tolerance policy for adverse events. As such, the Brain Imaging Research Center reserves the right to enforce any of the following policies. The policies are in place to ensure the safety of participants and staff members. Failure to comply with any of these policies will not be tolerated and may result in a participant being removed from a study or a staff member being asked to leave the scanner area.

Staffing Policies

1. At least two members of BIRC Staff must be present at all times during scanning regardless of study. This will include the MRI Operator.
 - 1.1. Additional MRI Safety and HIPAA trained individuals may be present during the scanning session. This may include students or collaborating research staff members.
 - 1.2. For non-BIRC scans, done by research staff outside of the BIRC utilizing the scanner, one member of the staff must be present during the scanning session at all times, in addition to the two BIRC Staff members. This person is responsible for escorting the participant to and from the BIRC scanner.
 - 1.3. The MRI Operator reserves the right to remove any individuals from the scanner area or console control room at any time.
2. The designated MRI Operator is the only person allowed to operate the scanner and immediately connected equipment. This includes the console computer, equipment in the equipment room such as cooling cabinets and preprocessors, as well as any related equipment in the scanner environment such as coils and phantoms.
 - 2.1. The MRI Operator may designate another individual from the BIRC Research Staff to handle equipment under their direct supervision.
 - 2.2. At no point, under any circumstances, is any other member of BIRC Research Staff or Collaborating Staff allowed to operate the scanner while an individual is being scanned. This includes any test scans or scans performed to evaluate task paradigms. If the MRI Operator is unable to perform a scheduled scan, the scan will be canceled and rescheduled for a time when the MRI Operator is available.
3. Only members of BIRC Research Staff are allowed to instruct the participants on how to perform tasks while in the scanner. This includes instructions given to the participant while they are being scanned and practice sessions done outside of the scanner.
4. At least one member of BIRC Staff must be present during sessions in the MRI Simulator. This may be the MRI Operator or BIRC Research Staff.

- 4.1. Additional MRI Safety and HIPAA trained individuals may be present during the acclimation session. This may include students or collaborating research staff members.
- 4.2. For non-BIRC scans, done by research staff outside of the BIRC, one member of staff must be present for the session in the MRI Simulator. At no time, under any circumstances, is collaborating staff allowed to operate the MRI Simulator.
- 4.3. The MRI Operator and BIRC Research Staff reserve the right to remove any individuals from the MRI Simulator at any time.
5. Any staff member who is pregnant may not remain in the MRI Scanner Area while the gradients are operating and data is being collected. While the scanner is at rest, pregnant staff members may work on or around the scanner; however, exposure to the magnetic field beyond the 5-Gauss line should be kept to a minimum. According to the NIMH Council Workgroup on MRI Research Practices, there are no known negative effects of magnetic fields less than 4T on a developing fetus. However, as a general safety precaution, any pregnant staff member should limit time spent in the MRI Scanner Area.

Safety Training Policies

6. All individuals working with research participants must maintain up-to-date CITI and HIPAA training in accordance with UAMS policy. It is the responsibility of the individual to maintain current certifications and provide documentation of certification if necessary. Any individuals who have not yet completed CITI or HIPAA training or whose training has expired will not be allowed to interact with any participants or data. No exceptions.
7. MRI Safety Training will be required for anyone working with participants being scanned. This includes MRI Operators, BIRC Research Staff, and Collaborating Staff. Training will be updated on an annual basis. MRI Operators will provide information concerning how to complete training. It will be the responsibility of the individual to complete the training and return documentation of completion to the MRI Operator. Any individual who has not yet completed MRI Safety Training or whose training has expired will not be allowed in the scanner area. No exceptions.
 - 7.1. MRI Safety Training will be tiered, with MRI Operators being required to undergo the most rigorous training and Collaborating Staff the least. These tiers will be established on the basis of level of responsibilities of each staff member. For descriptions of these responsibilities, please see the Roles and Responsibilities section.
 - 7.1.1. If an individual moves up to higher tier, they must complete the MRI Safety Training required for that tier. This training must be completed prior to assuming the roles and responsibilities of the new position. For example, if a staff member who is currently a BIRC Research Staff member becomes an MRI Operator, before that person can assume the roles and responsibilities of the new position, they must first complete the necessary safety training for the MRI Operator tier.

- 7.1.2. If an individual moves to a lower tier, no new training will be required. Upon time to renew the training, the individual will complete the training required for the new tier.
- 7.2. MRI Safety Training will consist of a presentation of information and a post-test. The information will be appropriate to the roles and responsibilities dictated by the individual's tier.
8. MRI Operators must maintain current CPR training updated every 2 years. It will be the responsibility of the individual to maintain current training and provide documentation if necessary.

Participant Safety Policies

9. Participants in any study must pass a series of safety screening procedures before and during participation. Some procedures are not outlined above as they occur at various times in the study other than immediately before a scan. Refusal to complete any part of these procedures may result in the participant being ineligible for the study (if they have not signed a consent) or withdrawn from the study (if they have signed a consent). In some instances, it may be necessary to obtain medical records to verify safety of the participant. In those cases, BIRC Research Staff or the MRI Operator will use the BIRC Release of Information (ROI) form to obtain permission from the participant to pull their medical records.
 - 9.1. No information will be obtained from any medical records prior to participants signing an ROI. There will be no exceptions to this policy.
 - 9.2. The MRI Operator will be responsible for faxing ROIs to the necessary medical facilities. Records will be sent back to the MRI Operator, who will review the files and decide if it is safe for the participant to be scanned.
 - 9.2.1. The MRI Operator will use whatever resources necessary to make a decision on the safety of the participant. This may include, but is not limited to, the following: Reference Manual for Magnetic Resonance Safety, Implants and Devices: 2011 Edition, a medical doctor, reliable internet sites, etc.
 - 9.3. The MRI Operator will also be responsible for maintaining any medical records obtained on any participant, with emphasis on maintaining the privacy and confidentiality of each participant.
 - 9.3.1. The MRI Operator will keep all medical records and associated ROI forms together, along with the fax transmission report, in a locked cabinet in the MRI Operators office.
 - 9.3.2. If a participant for whom medical records have been pulled is eligible and signs consent forms, their medical records will be kept with that participants consent forms.

- 9.3.3. If a participant for whom medical records have been pulled is eligible but does not sign consent forms, medical records will be kept and filed with other participants' records who were not eligible.
 - 9.3.4. If a participant for whom medical records have been pulled is not eligible, medical records will be kept and filed with other participants' records who were eligible but never signed consent forms.
 - 9.3.5. To maintain thorough records, at no point will any medical records be destroyed while a study is active. They will be kept, filed as described above. Once a study is closed to enrollment, medical records for ineligible participants and participants who were eligible but never signed a consent form will be destroyed. Records for eligible participants who participated in a study will not be destroyed, but instead kept and filed as described above.
10. Research participants must undergo the screening procedures outlined above prior to entering the scanner area or having a scan performed. This includes the MRI Safety Screening Form and the SAFESCAN® ferro-magnetic detector. Refusal to complete part of the safety screening procedures will result in the participant being removed from the study.
 - 10.1. The MRI Operator will give final approval of the safety screening process prior to each subject being scanned. If the MRI Operator feels more information is necessary, they may ask as many additional questions as they feel necessary prior to scanning any individual.
 - 10.2. If any member of the BIRC Research Staff learns any information during the screening or participation process which may relate to a participant's safety during the scan, that information will be given to the MRI Operator and they will decide together if the participant is safe to be scanned.
 - 10.3. The final decision regarding safety of participants rests with the MRI Operator. They may refuse to scan any participant if they believe that the safety of the participant is a legitimate concern, regardless of reason.
 11. For the scanning session, each participant must comply with the following safety precautions. Refusal to do so will result in the participant being removed from the scanner area and the study. Scanning will not be performed if any of the following policies are not met.
 - 11.1. All participants must remove any clothing items that contain ferro-magnetic objects. This includes, but is not limited to, items such as belts, keys, bras with underwire, watches, hair pins, glasses, etc.
 - 11.2. Any participants with tattoos will be instructed to report any burning or rash-like sensations in the area surrounding the tattoo to the MRI Operator immediately. In the case of minor discomfort, the participant may opt to continue the scan; however, if significant discomfort occurs, the scan will be stopped.
 - 11.2.1. Participants with tattoos less than 30 days old may be required to wait to receive a scan until the tattoo has fully healed. Some exceptions to this policy may be made

depending on the location of the tattoo. The MRI Operator will decide if it is safe to scan the participant.

- 11.3. All participants must wear hearing protection. This includes ear plugs and headphones; both are mandatory.
- 11.4. All participants must wear a call button given to them by the MRI Operator. They must have the call button on them at all times during the scan.
- 11.5. All participants whose bare skin touches the side of the bore must have foam cushions or a blanket placed in between their skin and the sides of the bore.
- 11.6. Participants will be instructed not to cross their legs or clasp their hands, as they may create a closed RF loop and cause potential nerve stimulation.
- 11.7. In the case of scans using the chest pad to measure breathing, the chest pad will be placed on top of clothing. This is to prevent the risk of heating or possible burns.
12. Due to the weight limit of the scanner, no participants weighing more than 330lbs/150kgs can be scanned. Additionally, any participant under the weight limit that complains of discomfort in the scanner due to the size of the bore may request to be removed from the scanner at any time.
13. Constant communication must be maintained with participants during the scanning session. Participants will be instructed to use the call button to signal the MRI Operator if they begin to feel uncomfortable while the scanner is running. In between scans, staff, either BIRC Research Staff or the MRI Operator will be able to communicate freely with each participant. Additionally, at this time, the MRI Operator will verbally verify the participant's willingness to continue with the next scan of the session. Participants may request to be removed from the scanner at any time if they begin to feel claustrophobic or uncomfortable.

Scanning Adolescents

14. For any study in which adolescent participants receive research MRIs, a parent, legal guardian, or responsible family member over the age of 18 must be present at all times for the participant's scan. This is to ensure accurate and complete medical information can be obtained for the participant in question.
15. The parent/legal guardian/family member must be present during the completion of the MRI Safety Screening Form. A signature must be obtained on the MRI Safety Screening Form from the parent/legal guardian/family member who was present during completion of the form.
16. No policies or procedures will be changed or altered in any way for participants under the age of 18.

Emergency Policies

17. In the case of a medical emergency involving any illness or injury, the participant will first be removed from the scanning environment if possible. If it is not possible to remove the

participant from the scanner due to the risk of further harm or injury, efforts must be made to stabilize the individual.

- 17.1. In the case of a medical emergency, the MRI Operator will attempt to stabilize the participant while the BIRC Research Staff member calls for assistance. Emergency numbers will be posted at all times on the MRI Control Room.
- 17.2. If no outside assistance is necessary, the BIRC Research Staff member will assist the MRI Operator in stabilizing the participant.
- 17.3. At no time should a participant experiencing a medical emergency be left unattended in the scanner area.
- 17.4. Emergency equipment including crash cart and MRI-safe fire extinguisher will be kept in the MRI Control Room at all times. These will be routinely inspected and kept in proper working order.
18. In the case of a magnet emergency involving any individual, participant or otherwise, being restrained, pinned, or harmed in any other way by a ferrous object, the following policies and procedures will be implemented:
 - 18.1. First, an assessment of the severity of the situation must be done by the MRI Operator. If the situation is life-threatening to the individual, an emergency quench may be performed by the MRI Operator.
 - 18.2. If the situation is not life-threatening, assistance will be attained to determine the optimal way of freeing the individual without causing any further harm or injury. This may involve only the staff present or may require outside assistance.
19. An emergency quench of the magnet may only be performed by the MRI Operator, or by a member of the BIRC Research Staff under the MRI Operator's authority. In either circumstance, the magnet may only be quenched if the life of an individual is in jeopardy and no other solutions exist to ensure the safety of the individual. In the event of an uncontrolled or unplanned quench, all individuals within the scanner area (including any participants in the scanner during the quench) must evacuate as the rapid release of cryogenics may spill into the scanner area, making breathing difficult.
20. Any magnet emergency or emergency quench must be reported to the BIRC Director, any appropriate UAMS campus operations groups, and Philips. Incidents that require reporting to the Institutional Review Board will be reported according to institutional policies. It will be the responsibility of the MRI Operator to ensure all necessary reporting occurs.
21. In the event of a distress code being called over the UAMS intercom, scanning will be stopped and the participant removed from the scanner. Every effort must be made to ensure participant safety by following the suggested code-specific course of action. At no time during a code should the participant be left unattended or remain in the scanner area.
22. In the event of damage to the scanner or equipment or a failure of a system to perform properly, the MRI Operator, if not already aware of the situation, will be notified. If a malfunction occurs during a participant's scan, the scan will be stopped immediately and

participants and staff removed from the MRI Scanner Area until a solution can be found and implemented.

- 22.1. In the event a solution to the malfunction cannot be found in a timely manner, the participant's scan will be rescheduled for a later time convenient for the participant.
- 22.2. The BIRC Director will be informed of all scanner malfunctions and their solutions.

Collaborating Study Policies

23. Before any scans are performed for collaborating researchers, the BIRC Director must give approval for the study to use the BIRC MRI. Approval must also be granted by the BIRC Division Business Administrator. There shall be no exceptions to this policy.
24. After obtaining permission from the BIRC Director and Division Business Administrator, the collaborating staff should submit a protocol to the UAMS IRB. No scans will be performed prior to IRB approval.
 - 24.1. Any members of the BIRC who will interact with participants must be added to the staff listed in ARIA. This includes, but is not limited to, the MRI Operator, BIRC Research Coordinators, etc. All scanning procedures implemented as described in the "Procedures" section of this document must be included in the protocol.
 - 24.2. No procedures which have not been approved by the IRB will be used. A copy of the protocol and consent must be provided to both the MRI Operator and a member of the BIRC Research Staff.
25. The MRI Operator is responsible for designing an examcard corresponding to the scan tasks being performed. The examcard will be designed based on the tasks listed in the currently approved protocol. A member of BIRC Research Staff will program the tasks to be implemented in the scanner, unless a suitable version of the task already exists. A practice version, if needed, will also be programmed.
26. The MRI Operator or a member of the BIRC Research Staff will provide to the collaborating researchers information concerning safety in the MRI, procedures used when scanning, policies concerning scanning sessions, inclusion/exclusion criteria and any other information regarding the MRI that is requested by the collaborating research group. This includes a copy of the currently approved version of the MRI Safety Screening Form to be submitted in ARIA with other study materials. No scans will be performed prior to the MRI Safety Screening Form being approved for use in the study by the IRB.
27. Scan sessions will be scheduled through the MRI Operator or BIRC Research Coordinators. If a time is available, the MRI Operator or Research Coordinator will schedule the scan on the BIRC Scanner Calendar. At least 48 hours' notice must be given prior to scheduling a scan. There may be some exceptions to this policy, but the exceptions must be approved by the MRI Operator or Research Coordinator only. At no point will collaborating staff have access to the BIRC Scanner Schedule.

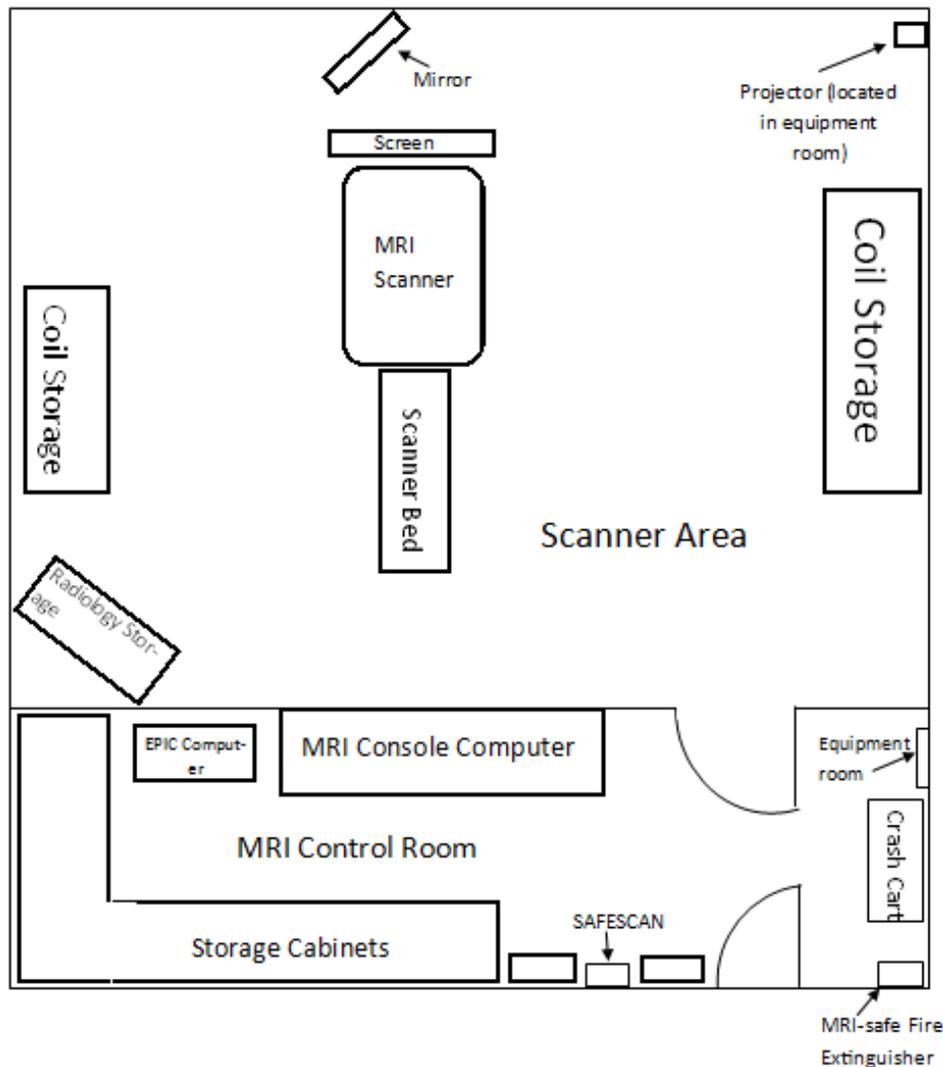
- 27.1. The BIRC currently shares scanner time with the UAMS Radiology department, with Radiology having use of the scanner in the morning hours (until 1pm) and the BIRC having use of the scanner in the afternoon (from 1pm).
- 27.2. No research scans will be scheduled during Radiology's time on the scanner. However, there may be some exceptions to this policy, with Radiology needing the scanner in the afternoon or the BIRC needing the scanner in the morning. These instances, while rare, must be coordinated through the current Chair of Radiology and the BIRC Division Business Administrator and may involve a tradeoff of scanner time. If this is the case, the BIRC will follow the instruction of the Division Business Administrator.
28. Any changes to the protocol and/or consent that modify the parameters of the scan or the implementation of the task should be communicated to both the MRI Operator and a Research Coordinator. The BIRC will be responsible for making the necessary changes to the scanner sequences and task paradigms. No procedures will be implemented without IRB approval.
29. The responsibility of ensuring compliance with the IRB protocol rests ultimately with the collaborating research staff. The MRI Operator and BIRC Research Staff will make every effort to ensure compliance of collaborating studies to the currently approved protocol and consent as well as the MRI Policies and Procedures, however, the BIRC cannot be solely held accountable for instances of deviations or non-compliance.

Visitor Policy

30. Visitors to the BIRC who wish to see the MRI Scanner must be cleared with the MRI Operator. They will also sign UAMS Confidentiality Agreements even if no PHI is to be involved in the tour.
 - 30.1. Signed Confidentiality Agreements will be filed with the MRI Operator and stored in a locked cabinet.
 - 30.2. If a visitor returns to the BIRC within 6 months of signing a Confidentiality Agreement, they will not need to re-sign a form. However, if it has been longer than 6 months, they must sign a new Confidentiality Agreement.
31. All visitor tours must be cleared by the MRI Operator and placed on the BIRC Scanner Schedule. No participants are to be scanned while the tour is scheduled. The MRI Operator is to be on hand at all times during the tour.
 - 31.1. Visiting PIs may observe a scan of a participant, provided that participant is enrolled into their research study.
 - 31.2. If, during a tour, the host would like to demonstrate a scan, a member of BIRC Research Staff may volunteer to be scanned. The MRI Operator is the only person allowed to operate the scanner and immediately connected equipment during a scan. For policies on scanner operation and staffing, see Policy 2.

32. The MRI Operator has final approval of all tours of the MRI Scanner Area/Control Room and Mock Scanner. The BIRC wishes to be accommodating to those individuals with an interest in the functions of the MRI Scanner, however, the confidentiality of participants and the safety of both participants and staff is of the utmost priority.

Appendix 1: MRI Scanner Room Layout



Appendix 2: Additional Information

ACR Guidance Document for Safe MR Practices: 2007

Shellock, F.G, & Crues, J.V. (2004). "MR Procedures: Biologic Effects, Safety, and Patient Care". *Radiology*, 232, 635-652.

NIMH Council Workgroup on MRI Research Practices: MRI Research Safety and Ethics: 2005