

TTNI Safety Policy

1. Regulatory Requirements for the Conduct of Human Studies

- a. TTNI and IRB Approval: The TTNI Protocol Review Committee and the Texas Tech University Institutional Review Board (IRB) must approve all study protocols conducted within the TTNI. Investigators interested in conducting research using TTNI facilities should download the project request form from the TTNI website located at: <https://www.depts.ttu.edu/research/ttni/getting-started.php>. Completed project request forms should be e-mailed to neuroimaging@ttu.edu.
- b. TTNI Safety Screening Sheet: Participants, or their parent/legal guardian, must fill out a TTNI Safety Screening Sheet on the day of their study prior to being scanned. The TTNI Safety Screening Sheet is available from the web site, <https://www.depts.ttu.edu/research/ttni/getting-started.php>. A completed and signed safety screening sheet must accompany the study participant for review by the MR technician before the study can be conducted. If the subject indicates on the sheet they have a risk factor or contra-indication for MR scanning, the study will be cancelled.
- c. Controlled Drugs: Controlled substances are **NOT** allowed at this time.
- d. Responsibility of Principal Investigator: It is the responsibility of the principal investigator and their research staff to insure the availability of the signed safety screening sheet, as well as confirming that the study protocol has IRB approval. A copy of the IRB cover sheet, showing the study approval date and end date, must be provided to the TTNI staff where it will be kept on file. If IRB approval for the study is expired or if the signed safety screening sheet is not available, the MR study will be cancelled.
- e. Staff Training: All research personnel working in the MRI control room (ESB 018B) must undergo MR safety training. **No researcher will be permitted to enter the MRI control room unless they are trained in MR safety.** Visitors may enter the MRI control room with TTNI consent *without* training when there are no research or medical scans being performed.
Training consists of the following:

- 1) Online course and test on MR safety (updated every 2 years)

- 2) Watching the MR safety video (updated every 2 years)
- 3) Signed and dated TTNI Safety Screening Sheet (updated every 2 years)
- 4) Signed and dated TTNI Imaging Policy Form (one-time requirement)

The two documents in items #3 and #4 can be obtained from the TTNI website <https://www.depts.ttu.edu/research/ttni/getting-started.php> .

The four elements of MR safety (online course and test, video, TTNI Safety Screening Sheet, TTNI Imaging Policy Form) will be tracked for each researcher by Texas Tech online training (i.e., Environmental Health & Safety) and TTNI.

2. Standard Operating Procedures for Medical Safety in the TTNI

- a. The physical and mental status of each subject will be informally evaluated by the MR technician and the study's principal investigator, or their research staff, before entering the MRI control room.
- b. All subjects and research staff will undergo formal screening for metallic objects before entering the TTNI. If objects are found they will be removed and stored in the locked boxes in the reception or changing areas.
- c. No one is permitted to go beyond the waiting and interview areas and into the MRI control room until the MR technician or TTNI Director gives clearance.
- d. Each participant, or parent/legal guardian, will fill out the TTNI safety screening sheet prior to participation in a MR study. Those with risk factors for MR studies, such as critically implanted magnetic objects (i.e., aneurysm clips, cardiac pacemakers etc.) will not be allowed in the magnet chamber Room 018BC) At the beginning of the study a copy of the safety screening sheet should be provided to the MR technician.
- e. All research staff that may accompany the subject into the magnet room must complete all aspects of MR safety training and must have an updated MR safety sheet on file and be approved by the MR technician or TTNI Director prior to the study. (see 1f above).
- f. On the 3T system, all subjects must pass through the ferromagnetic detector and the investigator has the option of having subjects change into scrubs to ensure that no metal is concealed by the participant. A member of the research team must be present during the study. The MR technician will **not** conduct the study alone.
- g. No ferrous metallic objects may pass the Ferr-Alert system mounted on the inside of the magnet room door. If the Ferr-Alert sounds an alarm, step outside of the magnet room and remove the object that caused the alarm.

TTNI policy is that the person that caused the Ferr-Alert alarm is **NOT** allowed to remain in the magnet room until the alarm is silenced.

- h. The door to the magnet room must be kept closed and locked at all times.
- i. All equipment necessary to conduct the study must be in place in the magnet room before the participant enters. After the participant is positioned in the scanner, no additional equipment can be brought into the magnet room. The MR technician is the only person who can enter the room or give permission to enter the room.
- j. No oxygen tanks can be brought into the TTNI magnet room. Researchers should pre-screen to exclude participants that require supplemental oxygen.
- k. A study will be cancelled if there is any breach in MR safety.
- l. In the event of an incident or emergency, the study participant **MUST** be removed from the scan room for evaluation and treatment. Use of a MR safe stretcher will be available to move participants out of the magnet room.
- m. Emergency medical service (911) is available. If there is an emergency, see section 6 below.
- n. A member of the research team must be present at all times during the study in order to address any questions or concerns the subject may have about the study. A member of the research team must be available to consent the subject and to run the stimulus program on the TTNI computer located in the control room.
- o. All subjects must be capable of walking to the scanner and getting into the scanner without assistance from other people or using devices such as wheelchairs, walkers, or crutches. If the subject requires any assistance, the scan will be canceled due to MR safety concerns.
- p. Incidental Findings: The TTNI staff and researchers are **not** authorized by the IRB to provide information about any scan. Any report given back to the participant must be approved by the IRB and be stated in the consent form prior to the research beginning. If a report has IRB approval, the investigator of the study will be responsible for purchase and will present a CD to the TTNI staff along with a copy of the approval prior to beginning the scan. TTNI will **not** provide blank CD's.

Summary of documentation required by the TTNI before a study may begin.

Provide a copy of the current IRB approval letter showing the end date of the project, or approved through date. Provide a signed TTNI safety screening

sheet and a signed IRB consent form prior to each participant being run in an MR study. Insure that all research staff completes the on-line MR safety training. Each researcher must take the online TTNI safety course and pass the safety test, read and sign the TTNI Imaging Policy Form, and watch the safety video once. Additionally, each researcher must have a completed and signed TTNI Safety Screening Sheet on file. Online safety course and test, MR safety video and the Safety screening sheet must be updated at least every 2 years and whenever MR safety status changes (e.g., new surgical implant).

3. Subject Stratification for Studies in the TTNI

Each proposed study will be evaluated by the TTNI Protocol Review Committee. The level of subject supervision required for an MR study will be based primarily on risk stratification as defined by guidelines of the IRB. General guidelines are listed below. **Moderate risk** and **High Risk** studies are **NOT** allowed at this time.

Adult Studies

Minimal risk is risk commensurate with ordinary daily life or with risks encountered in the performance of routine physical or psychological examinations. Minimal risk studies involve adult subjects who do **not** require anesthesia and who do **not** receive intravenous infusions, drug infusions, MR contrast agents, or restricted drugs (intravenous or oral). Minimal risk participants are monitored by the MR technician and the researcher accompanies the participant.

Pediatric Studies

Minimal risk is risk commensurate with ordinary daily life or with risks encountered in the performance of routine **physical** or psychological examinations. Minimal risk studies involve healthy pediatric subjects who do **not** require anesthesia and who do **not** receive intravenous infusions, drug infusions, MR contrast agents, or restricted drugs (intravenous or oral). A parent or guardian of pediatric participants may accompany the child into the MRI control room and only if absolutely necessary may they accompany the child into the magnet chamber room. At no time should a parent or guardian be standing or seated directly behind the MR technician. The parent or guardian should remain either in a dressing room or in the waiting room while the pediatric subject is in the scanner to ensure safety for all personnel.

4. Contrast Agents are NOT Allowed at this time.

- a. To discuss future studies requiring intravenous contrast agents, please contact the Director of TTNI (eric.walden@ttu.edu). Note that standard procedure requires that a physician be present when intravenous contrast is administered.

5. Emergency Procedures for Human Studies

- a. Call the emergency number for Texas Tech University (911) to request emergency medical service (EMS). It is very important to identify the location of the emergency, which in this case is room 018, basement of Experimental Sciences Building on TTU's main campus.
- b. Move the subject from the scan room to the Medical Care (interview) room and remain with the subject until EMS arrives. An emergency stretcher is available to move the participant out of the scan room.
- c. Do not bring additional emergency equipment into the scan room –the magnet is still on and the no admittance policy is still in effect during a medical emergency.
- d. If there are 2 research personnel, one person stays with the subject and the other will direct EMS to the participant in the TTNI.
- e. To meet and direct EMS to the subject, go to the ESB Loading Dock (NE corner of building). Escort EMS personnel into the building to evaluate the subject.
- f. Call or page the principal investigator of the study and call a physician collaborator if your study has one.
- g. After the emergency, report the adverse event to the IRB.