Human Studies

1. General guidelines for human research. Some general guidelines for human research studies in experimental protocols conducted at the BIC are:

   All subjects will be evaluated by an attending physician, principal investigator, or a level 2 user, with regard to their physical and mental status before entering the control or magnet room. Subjects deemed to have an unsatisfactory status will not be permitted to participate at that time.

   All subjects and visitors will undergo screening for metallic objects before entering the control room, and those with critically implanted metallic objects (i.e. ferromagnetic aneurysm clips, pacemakers etc.) will not be allowed in Area A.

   All subjects are required to change into a surgical scrub shirt (provided by the BIC) for brain studies, and full surgical scrub garb (again, provided by the BIC) for all other studies.

   Studies involving human subjects require prior approval of the UT IRB. This includes pilot studies. It is the responsibility of the Principal Investigator to ensure that IRB approval for all studies is current. The Operations Administrator will ask investigators for copies of current IRB approvals, and maintain them for the duration of the study.

   Studies involving human subjects must meet standards for scientific merit and ethical work. Evaluation of this requirement may be undertaken by the Executive Committee for approval of new studies.

   The PI or his or her designee will ensure that all human subjects (and guardian, when appropriate) sign an IRB-approved informed consent form before entering Area B. The subject will receive a copy of the signed consent form and the PI will retain the original.

   All subjects will complete the standard MRI Subject Screening Form that is on REDCap. The level 2 certified user will review the screening form and make final determination on the subject’s fitness to participate in the MRI study. The signed screening forms will be maintained in REDCap by the Operations Administrator.

   In the event of an incident or medical emergency requiring medical attention to subject or other persons, the level 2 certified user on duty shall first call 911 (or instruct an alternate individual to call) and remove the person from the magnet room, so that the emergency response team will not need to enter the magnet room. If this is not possible, the magnet must first be quenched to enable access by emergency medical staff and their equipment. The latter situation is to be avoided if at all possible, but examples of situations requiring a quench might include pinning of a subject by physical interaction with magnetic fields, or a traumatic back or neck injury where a person is severely injured and cannot be mechanically stabilized sufficiently to move them outside of the 50G line for treatment. To assist operators in the event of an emergency, task lists for emergency procedures are kept in a blue binder in the magnet control room.

   In the event of an obvious pathological or structural anomaly in an MRI scan, the investigator will follow the step-by-step procedures detailed in Appendix D.

   Whenever minors are to be enrolled in imaging studies conducted using BIC facilities, the investigators must follow the procedures and policies provided in Appendix E.

2. Responsibilities of level 2 user. At least two people, including one level 2 certified user, must be present whenever an MR system is being used to scan a human. Before any scanning procedure, the level 2 user will:

   Inform the subject that peripheral nerve stimulation may occur, and describe the nature of the sensation.

   Instruct subjects not to clasp their hands, cross their legs, or otherwise configure their body parts in such a fashion as to create a conductive loop that can increase the possibility of stimulation and RF burns in the magnet.

   Ensure that all cables from all devices including physiologic monitoring, RF coils, response boxes and other equipment is not to touch the human subject. Ensure that other cables or devices do not form a loop, either large or small within the bore of the magnet at any time.

   Ensure that all human subject anatomy is shielded from bore walls and that all cables and devices are spatially buffered from the human by a sponge or blanket thickness of at least ¼ inch that can be easily maintained throughout the entire MR examination.

   Be responsible for instructing the subject regarding the use of earplugs to prevent acoustic noise issues and ensure that the subjects are properly wearing this ear protection.

   Maintain continuous visual, verbal, or electronic (e.g., squeeze ball or intercom) contact with the subject.

   Instruct subjects to inform the operator if they experience discomfort.

   Terminate the scan if the subject complains of discomfort, pain, or fear.

   Complete a report of any incidents involving severe discomfort or pain, including a description of the associated circumstances (imaging parameters, dB/dt value, level of pain, etc.), and submit this report immediately to the MRI Operations Administrator. The individual investigator is responsible for reporting any incidents to the IRB as well as to the Operations Administrator. All consent forms for studies that might induce peripheral nerve stimulation should include language informing the human subject of the potential for peripheral nerve stimulation.
3. **Administration of exogenous agents.** All MR examinations that include the administration of contrast agent or other pharmaceuticals require the presence of a physician licensed to provide health care in the state of Texas. All examinations that include the administration of contrast agent must follow the relevant BIC policies and procedures, and the risk of NSF (kidney problems, past and present) must be included on screening and consent forms for all subjects. Investigators using contrast agent are responsible for maintaining a stock of pharmaceuticals and delivery equipment suggested by the agent’s manufacturer to manage potential life-threatening hypersensitivity, as well as a properly maintained and fully-stocked crash cart. Before administering a contrast agent to a subject with any renal insufficiency, the subject’s Glomerular Filtration Rate (GFR) must be measured and fall within accepted limits. MRI contrast agents are NOT allowed to be administered in the NHB facility. Contrast agents may only be administered in the HDB facility if one of the trained technicians or the paramedic is on hand and booked on their schedule to do the injection.