

Human MRI/MRS Guidelines

1. General statement: The objective of this document and the policies/procedures developed by the ad hoc AMRIS committee is to facilitate human research on the Siemens Allegra 3T short bore (3T/60) and GE 3T whole body (3T/94) systems. To complement the efforts of the AMRIS committee, the MR community is encouraged to set up a “3T Users Group” which meets on a regular basis. This group can help identify issues that need to be addressed as well make suggestions to the AMRIS Director and Associate Directors.

2. Categories of subjects: The AMRIS committee recognizes that the risks and needs associated with human studies vary depending on the subject population. The following subject categories have been identified and will be referred to during discussions:

- I:** Healthy subjects
- II:** Stable ambulatory subjects
- III:** Potentially unstable subjects*

*Note that ALL subjects that are in-patients at Shands are considered to be potentially unstable and as such are classified as category III. Likewise ALL psychiatric patients treated in a closed facility or on the ICU should also be classified as category III, whereas all other psychiatric patients *can* be considered as category II subjects.

3. Billing issues: After much discussion the following MR slots have been set up:

Prime time (\$400/hr base rate):	Monday –Friday 8:00 – 17:00
Non-prime time (\$300/hr base rate):	Monday –Friday 17:00 – 20:00 Saturday – Sunday: 8:00 – 20:00
Off-time (\$200/hr base rate):	Monday –Friday 20:00 – 8:00 Saturday – Sunday: 20:00 – 8:00

Prime time: During prime time a clinical technician** will be available to run the study. All studies involving category III subjects, experiments requiring gadolinium*** and studies requiring sedation will need to be performed during this time.

Non-prime time: During non-prime time no clinical technician is available. This time is reserved for human category I and II studies, animal studies, phantoms and technique development.

Off-time: During off-time no clinical technician is available. This time is reserved for human category I and II studies, animal studies, phantoms and technique development.

** At this time a clinical technician is only available from 8:00-12:00. If other times of technician support are needed special arrangements with the chief MR technician Mary Ellen Bentham

(265-0106, benthme@radiology.ufl.edu) can be made. Studies utilizing their own operator can be run at a rate of \$375/hr.

*** Note that the base rate does not include Gadolinium studies (see below).

4. Studies requiring a clinical technician: The following studies will need to be performed in the presence of a certified clinical MR technician during prime time:

- (a) Category III subjects
- (b) Studies requiring *injection* of paramagnetic contrast agents such as gadolinium (Gd)
- (c) All studies requiring *sedation*

Currently the clinical MR technician for the 3T/60 is available from 8:00-12:00 or by special arrangements, Mondays - Fridays. Given the limited availability, studies requiring a clinical MR technician will be given priority to sign up for these time slots. It is anticipated that additional guidelines will need to be set up as the 3T/60 system gets more heavily occupied. The availability of clinical MR technician support for the 3T/94 will be established once this new MR system is installed.

5. Training of new operators: Since several users have expressed a strong interest in having their own staff serve as operators, the following procedure has been set up. Hands-on training of the MR scanner will be provided by the AMRIS MR technologist (Xeve Silver or Mary Ellen Bentham) or an already approved operator. The minimum of training is not dependent upon the number of hours but rather whether the MR technologist feels that the potential operator is ready to run the machine. If an already approved operator is used for training, the potential new operator will have to demonstrate his / her ability to operate the MR scanner to the MR technologist (Xeve Silver or Mary Ellen Bentham) for approval. The training can be accomplished while running the investigator's studies or by signing up for a separate time slot. These time slots will be charged as outlined above. All operators will also have to demonstrate safety competency as discussed below and complete the MR operator approval form (appendix).

6. Safety procedures:

Phone numbers: All emergency phone numbers are posted in the MR facility so that they are readily available to all users. In addition, the contact information of multiple support staff is posted.

Screening form: A standard screening procedure has been established. All subjects are required to complete a standardized MR screening form (see appendix). All users are encouraged to contact the clinical MR technicians (phone: 265-0106) or Dr. Ilona Schmalfuss (beeper: 727-6668) if there is **any** concern in regard to the safety of their subjects. The appropriate contact information is posted in the MR facility. There is no charge associated with contacting the support staff and all users are highly encouraged to do so, when needed.

Remember: **Better SAFE than sorry!!**

Orbital X-rays: All subjects at risk of having metal in their eyes (*e.g.*, metal workers, workers, *etc.*) require an orbital X-ray. Information in regard to how to order a plain X-ray film is provided in the appendix as well as the procedure for billing.

Safety training: All operators and users will have to demonstrate MR safety competency. In order to minimize the burden on current users, a distinction will be made between new and experienced users.

ALL USERS: All MR users are required to watch the MRI safety tape as currently required by MBI-UF's AMRIS facility.

ALL NEW OPERATORS: All new users will have to complete the following two steps.

(a) Take the MRI safety module test at http://www.t2star.com/safety_1/MR_Safety.pdf. This website provides 14 pages of text about MRI safety and provides a lot of in depth info. This test cost \$15 and provides 1 hour CME credit. The potential new operator will have to provide a copy of the CME credit confirmation to be approved as operator.

(b) Read the most recent update on MR safety published by the American College of Radiology: "American College of Radiology White Paper on MRI Safety." This article, written by E. Kanal can be down-loaded from their website http://www.acr.org/dyna/?doc=committees/mr_safety/safe_mri.html. A copy is also placed in the "Human research user manual" in the 3T/60 scanner suite.

7. Gadolinium (Gd):

- (a) There is an extra charge of \$50 for an experiment involving injection of the paramagnetic contrast agent, Gadolinium (Gd).
- (b) Gd experiments can only be performed in the presence of a clinical MR technician.
- (c) When scheduling, PI's need to indicate "Gd" experiment.
- (d) Order information for Gd is made available (see Appendix).
- (e) Ordering of Gd is the responsibility of the PI.

Note: The \$50 charge will be utilized to offset the expenses made by the MBI-UF's AMRIS facility to replenish the necessary supplies (*e.g.*, IV lines, syringes, *etc.*) needed for the contrast injector.

8. Special requirements for Category III subjects: Studies on potentially unstable subjects (*i.e.*, Category III) will require the presence of a physician, nurse or physician assistant with current BLS or ACLS certification. The organization of such an individual is the responsibility of the principal investigator. Note that this requirement includes psychiatric patients classified as Category III, as delineated above.

9. Scheduling: Weekly advance reservations can be made on-line. The advance reservations will close Wednesday at 5:00pm for the following week. Walk-on reservations will be accommodated and should be made directly with the AMRIS Office Administrator.

10. Cancellation: We recognize that as the number of users increases, the cancellation policy will need to be reviewed and possibly modified. However, at the present time cancellation will need to be made less than 24 hours prior to the scheduled time. Individuals that make last minute cancellations a habit and/or if use claustrophobia as an unfounded excuse, will be considered abusers and their behavior will be addressed in the 3T Users meetings! In addition, frequent abusers will receive lower priority in future scheduling.

11. New Study:

Forms: *Prior* to initiating an MR study the Principal Investigator will need to obtain IRB approval for the study and complete an “**MRI Protocol for Human Subjects**” form (see Appendix). The latter form provides details on the sequences, coils and archiving procedures that are required for the study. The IRB approved consent form and the completed MRI Protocol for Human Subjects form should be send to the AMRIS Director.

Preemptive Assessment/Preparation for “Standard” and “Non-Standard” Sequences: Prior to initiating a study the MR staff will perform a “dry” run, together with the investigator. This dry run is performed at no cost. Based on the dry run, the MR staff will be able to advise the investigator on any potential problems that may arise and give them an estimate of the required MR scanner time. After the initial assessment, one of the members of the AMRIS committee will sign the MRI Protocol for Human Subjects form and an encumbrance number is assigned. If the required sequences are “Non-Standard” (*i.e.*, those not regularly used on our 3T scanners), then the Principal Investigator may need to collaborate with another MR researcher to help develop these sequences. The MR staff is qualified to help implement the protocols **not** to design the protocol. As described below in #12, recognize that the development of new or modified sequences will likely involve scanner and personnel time and that the costs for this time *will* be charged to the Principal Investigator. If there is disagreement whether a sequence is standard or not, the Associate Directors/Director will make the final decision.

Note: Users with limited MR expertise are advised to contact a MR researcher to help design their MR protocol. As described above for the development of new/revised sequences, the MR staff is qualified to help implement the protocols **not** to design the protocol.

12. Development and trouble shooting:

Development time: Since technical challenges occur at one time or another with all studies, a minimum number of hours will be set aside for development time. Access to the scanner for this purpose needs to be requested by the investigators for individual studies using the MR Protocol for Human Subjects form. A maximum of 2 hours can be requested for development time and only for Non-Standard procedures. Development time is provided at no cost and requires specific approval from the AMRIS Director.

Trouble shooting: If there is a technical problem with the scanner, trouble shooting time can be scheduled directly and only with the designated technician or technical staff. AMRIS technical staff will be present during trouble shooting. There is no charge for trouble shooting time.

13. Request for pilot data: AMRIS is establishing a system that allows for **pilot** data collection at no cost. In addition to finding funding sources to help offset the costs of this program, the following procedures for application are being discussed:

- (a) Number of scanning hours: No more than 10 hours
- (b) Proposal: 2 pages in which to present description of need, specific aims and justification
- (c) Evaluation committee: 2 people (3 in case of conflict) will review the proposal and make a recommendation to the AMRIS Director for approval.
- (d) Executive Director of MBI-UF: Authorizes the no-cost scanning time and a billing code is established. [If greater autonomy is given to the AMRIS Director, as is the current plan, then he/she would be the person designated to make this final decision since the cost of providing this “free” scanner time will be borne by the AMRIS budget.

14. Use of facility for imaging animals of excised tissues: It is recognized that in addition to imaging human subjects, the MBI-UF’s AMRIS 3T/60 will also be used to image live animals and excised tissues and as such certain additional policies are required.

- (a) **Scheduling of examination time:** 15 minutes should be added, at the user’s expense, to the examination time to allow for cleaning. Excised tissues (*i.e.*, body parts) should be imaged at non-prime or off time, preferentially at the end of the day to allow for sufficient ventilation of the facility.
- (b) **Cleaning of the scanner:** After the examination of each animal or excised tissue the table, coil and other surfaces as needed should be cleaned with 1% bleach solution followed by 70% ethanol solution or Virex solution. In addition, fragrance spray should be used to avoid undesirable odor. Under no circumstances, is it allowed to leave body parts in the MRI facility.
- (c) **Entering and leaving of the MRI suite:** Please be sensitive towards human subjects and patients waiting for or finishing up an MRI examination while bringing animals in or out of the MRI suite. Before bringing the animal into the MRI suite, check to see if the scanner is in use. If so, please wait with the animal to be scanned in the alcove adjacent to operator room till the human subject is out of the facility. Use discretion when leaving the MRI facility.

15. Data management: Data should be removed as soon as possible from the scanner after the examination. The MRI technician has the right to remove all data older than one week.