UM Center for Brain Imaging Research (CBIR)

Procedures and Regulations

PROCEDURES AND REGULATIONS

Fee

The fee is $500 per hour for scanner use with MR technician assistance, for NIH funded studies and for most academic projects. Additional time is assessed in increments of $250 per half an hour within the same session. For each session, scan should be booked at unit of 1 hour for the first hour and then every half an hour. The fee is $700 per hour for for-profit company research projects or for projects requiring priority scanner scheduling due to relatively fixed study schedule.

There is no time allocated between sessions. Each session should include sufficient time for orderly start and end of the scanning, including time for the subject to enter the MR suite, complete validation of safety checklist, and be positioned into the scanner, applications of any ancillary experimental equipments, and non-rushed time for safe exit from the scanner. Typically, one should arrange scanning tasks for no more than 45 minutes for each 1 hour session, depending on the tasks involved.

Safety

The safety of visitors to the Center whether or not research participants in a study, and of the Center staff is of paramount importance and takes precedence over any research considerations and over the convenience of any investigator. For this reason, the Center has prepared a manual of safety procedures (see MR Safety Manual), which is strictly adhered to at all times.

Type of Imaging

The Center is prepared to study, as part of a research protocol, normal adults, elderly participants, adolescents, and patients with stable conditions compatible with MRI imaging. Pharmacological imaging studies are supported and are our main focuses. The Center has a 32 and 12 channel head coils, a 12 channel full body coil, knee coil, neck coil, spine coil, and several specialized small coils. There is an Invivo behavioral task presentation system for fMRI (Esys). This is the primary behavioral task presentation system. It uses E-Prime 2.0 and lower versions can be accommodated. Other presentation system and software can be accommodated in collaboration with center staff. Research imaging tools, sequences, and imaging analysis expertise are in all areas of fMRI, in brain structural, DTI, ASL, spectroscopy, and whole body imaging in adipose tissue and vascular imaging research. A high resolution MR Eye tracker (Cambridge Research), and MR compatible physiological and IV equipments are available.

Incidental Clinical Findings

The studies to be conducted at the Center are research related, and not for clinical purposes. The Center does not routinely review imaging data for clinical Version 1.0 Last

modified March 24, 2012 2 implications. On occasion, incidental findings may be identified and need to be investigated medically. Any such potentially significant medical finding will be discussed with the Principle Investigator or his/her representative. It is the responsibility of the Principle Investigator of each protocol to formulate procedure on reviewing or managing of incidental clinical findings and to secure IRB approval of the procedure pertinent to each protocol.

Personal Identifiable Information

A participant to be scanned is given an ID (NID: Nxxxxx) that is assigned for each participant to be scanned, using the *Neuroimaging Participant Registration* database. Each participant can have additional IDs to be provided by the study team or the project's investigator (for example, a MRPC#, a Subject ID or S# or a number assigned by a particular study, all are optional). These numbers are to be entered during patient registration on the MR console and will be part of the imaging data file. No personal identifying information should be in the MR imaging data file.

Basic protocol and demographic information are entered into the *Neuroimaging Participant Registration*. This registration should occur ideally before scheduling so that the NID is generated and used for scheduling and all subsequent paper and digital documents. Basic participant information including personal identifiable information is be recorded separately when NID is generated and will be stored separately from the imaging data. Individual investigators are responsible for keeping records associated with the IDs in order to identify the raw imaging data collected in the Center.

Research Volunteer Procedure

Each investigator is responsible for obtaining IRB approval for his/her study and for providing the Center with the initial approval documentation. Adherence and monitoring of compliance to the protocol and any subsequent amendment, modification, and continuous review are the responsibility of the investigator and his/her staff. Investigator and his/her representative are responsible for explaining informed consent to every participant and for having every participant sign the informed consent form. Only consented participant following the approved protocol should be brought into the scanner. No participant can be scanned without a signed valid informed consent form. The signed consent forms must already be obtained prior to the scan being performed. A MR safety screening should be performed during the consenting or screening process. On the day of the scan, a copy or a photocopy of this form needs to be reviewed and signed off by the MR operator before the participant can enter into the magnet. Alternatively, another MR safety screening should be filled out at the day.

MR operator is responsible to 1) review the metal screening form with the participant and ensure safety, or contact a physician if unclear of safety, before allowing a participant to enter the magnet room; 2) review of de-metaling with the participant.

Metal screening is a team process, the research staff who brings the participant to scan should share the same responsibility above. Similarly, staff conducting consent should carefully describe and educate each participant on metal screen and MR safety.

Participants with a history of cerebro-vascular disease, neurosurgical procedures, or accidents, in connection with which metallic objects or particles might have been lodged inside soft tissue of brain or eye, will need to submit a medical report, signed by a physician, stating that it is safe to undergo an MRI. This report needs to be filed together with the metal screening questionnaire.

Research Proposals

All scanning projects are to be submitted to the Proposal Review Committee for scanning request. For funded proposals that have completed competitive review, a one page request should be filed. Additional scanning hours for piloting the tasks can be requested.

For pilot projects that are requesting for free pilot scan hours, an application should be submitted. Each pilot proposal will be reviewed by two or more referees from within or outside the committee as appropriate. Requests for pilot studies are to be accompanied by a brief description of the proposed study in which the hypothesis is clearly stated along with a rationale, description of the participants to be scanned. There also should be a brief description regarding the type of analysis to be performed. A description of the sources from which the investigator plans to seek funding once the pilot studies has been completed. The proposal also must include the names of any personnel involved in obtaining MRI data, and their qualification (or plan to be trained) to run the study. Proposals should be 2 to 3 pages in length. Approval of a proposal depends on its feasibility; merit and availability of time on the magnet, as assessed by the Committee, and on securing IRB approval by the responsible investigator.

Requests for approved and funded studies also require a brief request (1 page and no more than 2 pages), similar to the one outlined above, to assist the Committee in deciding how the Center is best to assist the proposed studies. Before submitting an external grant application that involves MRI scans, the investigators are encouraged to contact the Director or Associate Director and make certain the Center is prepared to commit the resources necessary for the particular study. The Center will not be required to honor scanning requests for funded studies involving unusual imaging arrangements unless a prior agreement was reached.