RCBI MRI Policies & Safety Procedures

3/15/18

Training
Before conducting research using the MRI, all study personnel who will be present during the MRI study must take and pass the RCBI MRI Safety course. This includes viewing a video, reading the RCBI Safety Policies & Procedures, MRI Safety Issues, Emergency Procedures and taking a test. Once this is completed you may apply for card access to the control room and you may then start scheduling study participants. Contacts and further information on scheduling will be provided by the MRI technologist.

Screening Policies

All persons (including the study participant, parents, attendants, etc) entering the MRI scan room must undergo a safety screening by the MRI technologist or other authorized personnel. All subjects entering the magnet room should fill out an RCBI MRI Screening Form just prior to the scan, and the person operating the scanner must confirm their responses verbally. Copies of the Screening Form can be found on the shelves at the rear of the console room, in the waiting room on the counter or downloaded from the RCBI website. Screening of study participants must be done just prior to entering the magnet room, even if they were previously scanned and the form is on file. Only after the operator of the magnet has done the final screening will the participant be allowed to enter the magnet room. Keep in mind if your study has the subject come in for a MRI on two different days you will need a screening form for each day.

You MUST prescreen all of your study participants to ensure they will be safe to scan. If you are unsure if an item is safe, visit the website www.mrisafety.com or contact the MRI technologist. The prescreening process will eliminate those people with an unsafe item without wasting a scanning slot. An updated list will be given out after the safety training to help guide you in the prescreening process.

There are a vast number of medically implanted devices on the market. If a study participant has an implanted device, have them provide documentation for the device if at all possible. Usually a patient will be given a card after the device is surgically implanted that gives the device manufacturer, model name, model number and the maximum field strength in which it is safe. Remember, a device that is safe at another MRI site may not necessarily be safe here, so we need to know exactly what the device is. If you ever have any questions regarding MR safety, please ask the RCBI MRI technologist.

There are titanium aneurysm clips that are safe in a 3T magnet but we do not scan them. The current standard is for a radiologist to document its safety. Since we do not have a radiologist on staff, all aneurysm clips are contraindicated for a scan. The same applies to pacemakers and implanted cardiac defribillators that are safe at 3T. We do not scan them. ALL pacemakers and ICD’s are contraindicated for a scan.

Since there may be a time when you (as the study investigator or team member) will have to enter the magnet room, all study personnel must also fill out a screening form. Although this form need only be filled out once, if there is any change in your medical history (such as metal in the eye or surgical implants), it will be your responsibility to inform the person conducting the scan and to update your form.
People in the Control Room

Only personnel associated with the current study will be allowed in the control room. In other words, if there is a study in progress, which you are not a part of, you can not enter the control room until they leave. If you are running a number of studies back to back you can not bring your second subject into the control room until after the first subject has left. All personnel in the control room during a study must have a current CITI number. At no time will spouse, friends, etc of the study participant remain in the control room. It is a standard MR safety procedure to have only MR safety trained personnel in the control room. There are also privacy concerns and overcrowding issues. We do have a very comfortable waiting room for the study participant’s family/friends.

At least, one member of the research team must be present in the control room throughout the duration of the study. The RCBI provides support for operating the magnet by providing an MR technologist. However, it is the responsibility of the investigator team to (1) bring the patient to the control room and introduce him/her to our MR technologist; (2) explain to the patients what will be required from him/her as being part of the study; (3) inform the MR tech of the type of images to be acquired; (4) provide help and follow directions of the MR tech in case of an emergency; (5) take charge of the patient once the imaging session is finished. It is mandated by the IRB that the PI or his/her representative take the responsibility for consenting the participant and making sure that all other procedures leading up to and following the actual scanning session are followed. The RCBI staff cannot, legally, take on this responsibility. So someone directly involved in the study itself must be physically present at every scanning session.

Sedation Policy

If your subject requires a drug for claustrophobia, we require that you have a medical doctor or authorized nurse on site in the MR suite who will monitor the patient for the duration of the scan. This person must have successfully completed the RCBI MRI Safety Course prior to the scan.

Pregnancy

While there are no known risks associated with performing an MRI on a pregnant woman, no studies on the long-term effects of RF tissue heating to the fetus have been done. It is standard MR safety to only perform scans on pregnant women for medically necessary reasons. Therefore it is our policy not to scan pregnant women. We do not give pregnancy tests so if your participant is unsure we will not scan her. Except for members of the research team, women who are pregnant (including a pregnant parent or spouse of a study participant) are not allowed into the scan room at any time.

Image Release Policy

If you have not received consent for image release, you CANNOT give the study participant an image of their brain. Under no circumstances should you release a full volume of images to a study participant. The policy of the center is to release only one slice view. Further information regarding this restriction may be found on the RCBI Wiki page.
Scanner Operator

Only RCBI-approved personnel may operate the MRI console. Except by prior arrangement and approval of the RCBI Director or Associate Directors, this will be the RCBI staff MR technologist.

Time Slots

The time you schedule (which is the time you will be charged) for your study will include total scan time, setup and breakdown time (ex: room setup, positioning, cleanup) and final screening. This takes about 10-15 min depending on the study. So if your total scan time is 45min, you can’t book a 45 min scanning slot. You must be leaving the control room (not the scan room) at the end of your reservation time.

In the event there is a scanner malfunction such that you will not be able to finish your study within your reserved time, you will have to reschedule your study. We *do not* back up the schedule. **If you are late for your reserved time, you will still be charged for that time.**

To keep scheduling fair only reserve time on the calendar when you actually have a subject. Fees will be applied to those that consistently overbook or reserve time before they have a confirmed subject.

If you have scheduled time on the calendar and you cancel that time less than one hour in advance, you will be charged a fee of $125 (equivalent to 15 minutes of scan time). This does NOT apply to legitimate no-shows by patients, but such no-shows should be followed immediately by an updating of the calendar so that other users are aware of the now open scan time.

**No names** are to be used on the RCBI scanner or mock magnet calendar. You may use the subject number or the name of the study.

Any exceptions to these policies must have prior approval of Dick Aslin.

Mock Magnet

The mock magnet is available to all users at no charge for training purposes only. There is a calendar and you must sign up for it. Please, only sign up time that you need and do not "pad" the time. If your subject cancels please be mindful to other users and take the time off the calendar.

If you need space for non training activities you can use the mock room only if it is available but you can not book it in advance. If you need to book your non training time then the conference room is available but you will need to sign up for this room.

Incidental Findings

In the event an incidental finding occurs with a subject, the data is sent to a radiologist for a reading. The fee for this radiology service is $55 per subject and will be billed to your account after the scan is read. Once the radiologist has sent the report it is the responsibility of the PI to notify the subject of the abnormality.
**Data Storage**

The RCBI charges a fee for data storage based on the amount of data stored in both your user accounts and data folders. If you do not wish to keep your data on our systems and thus incur a fee, you must remove your data from our system within 30 days of it being acquired. It is your responsibility to remove your data if you do not wish to pay for data storage.

The RCBI runs a weekly backup of all data, the costs for this are included in the storage fee. If you want the RCBI to only archive your data (at a reduced cost) this can also be done either one time (eg. when your study ends) or on a regular schedule. These archives will not be readily accessible nor are they backed up but a copy can be sent to you on request. Although we have employed industry best practices to safeguard your data, if you choose to only store archives of your data on our systems, you will be responsible to maintain the original data or a backup of the archive.

If you are unsure what data storage strategy to use, contact Evi Vanoost (vanooste@rcbi.rochester.edu) for more information on our systems and alternative strategies. You are at all times responsible to adhere to University and New York State regulations governing the unauthorized access, loss or theft of your data stored outside our systems.

We no longer provide CD's for data copies on a routine basis. If you want a CD burned it MUST be provided at the time of the scan.

**Data on the MR Console**

Now that the scanner is busier, the scanner disk fills up quickly. Therefore the data will only remain on the MR console for 2 weeks. Please check your data on the server as soon as possible after it is acquired. Since some of you have been removing older scans to your own storage solution or renamed them we cannot automatically verify that you have received the scans correctly.

**Reporting of an Adverse Event**

Investigators whose IRB-approved studies utilize RCBI resources should follow the reporting policies of the Research Subject Review Board (RSRB). Investigators should also notify the RCBI technologist, Patricia Weber (pweber@rcbi.rochester.edu) of any RSRB-reported Adverse Event/Unexpected Problem that has occurred during the use of RCBI facilities. Any RSRB-reported Adverse Event/Unexpected Problem that has involved RCBI procedures and may impact the safety of a research volunteer with future RCBI procedures (new implant found to be unsafe in the magnet, unsafe use of a device etc) needs to be reported to the RCBI. The RCBI reserves the right to suspend data collection until the investigator has cleared the issue with the RSRB. The RSRB may forward concerns they have received to the RCBI office.

**Phantom studies** (Relates to phantom studies done by researchers NOT subject studies)
Once the scanner disk reaches 68-70% capacity data needs to be removed otherwise there is a potential of the system to randomly corrupt data. If you have collected data and do not save it, the data tends to sit on the scanner console for a very long time taking up valuable space. Therefore, after you scan, it is your responsibility to either save the data or delete it. **AFTER TWO WEEKS. ANY OF YOUR UNSAVED DATA THAT IS ON THE CONSOLE WILL BE DELETED WITHOUT NOTICE.**