UR CABIN MRI Policies & Safety Procedures

Training

Before conducting research using the MRI, all study personnel who will be present during the MRI study must take and pass the UR CABIN MRI Safety course. This includes viewing a video, reading the UR CABIN Safety Policies & Procedures, MRI Safety Issues, Emergency Procedures and taking a test. Once this is completed you may then start scheduling study subjects.

Screening Policies

All persons (including the study subject, parents, attendants, etc) entering the MRI scan room must undergo a safety screening by the MRI technologist. All subjects entering the magnet room should fill out an UR CABIN MRI Screening Form **just prior to the scan**, and the MRI technologist must confirm their responses verbally. Copies of the Screening Form in the waiting room on the counter or downloaded from the UR CABIN website. Screening of study subjects 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 MRI technologist has done the final screening will the subject 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 subjects 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 our Operation Manager, Renee Stowell. The prescreening process will eliminate those people with an unsafe item without wasting a scanning slot.

There are a vast number of medically implanted devices on the market. If a study subject 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 contact Renee Stowell.

There are titanium aneurysm clips that are safe in a 3T magnet but we ***do not*** scan them at this facility. 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*** allow them to be scanned. ***ALL pacemakers*** and ***ICD's*** are ***contraindicated*** for a scan ***here at the UR CABIN.***

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 our Operations Manager, Renee Stowell, and to update your form.

People in the Control Room

Only personnel associated with the current study will be allowed in the control room at that given time. 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 subject 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 subject'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 UR CABIN provides support for operating the magnet by providing an MR technologist. However, it is the responsibility of the investigator team to (1) bring the subject to the control room and introduce him/her to our MR technologist; (2) explain to the subjects 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 subject 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 subject and making sure that all other procedures leading up to and following the actual scanning session are followed. The UR CABIN 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 or anxiety, we require that you have a medical doctor or authorized nurse on site in the MR suite who will monitor the subject for the duration of the scan. This person must have successfully completed the UR CABIN 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 subject 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 subject) 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 subject an image of their brain. Under no circumstances should you release a full volume of images to a study subject. The policy of the center is to release only one slice view.

Scanner Operator

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

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 $150 (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.

Any exceptions to these policies must have prior approval of John Foxe.

Mock Magnet

The mock magnet is available to all users at no charge for training purposes only. There is a Mock Magnet resource listed on Calpendo and you must book it like you would the scanner. 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.

There is also an assessment room available for booking as a resource on the calendar as well. 1B130 – is reserved for MRI subject assesments.

Incidental Findings

In the event an incidental finding occurs with a subject, the data is sent to a neuro-radiologist for a reading. The radiologist will email the appropriate PI about the findings. It is the responsibility of the PI to notify the subject of the abnormality.

Data Storage

The UR CABIN 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 UR CABIN runs a weekly backup of all data, the costs for this are included in the storage fee. If you want the UR CABIN 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 (evi_vanoost@urmc.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 data on CD's.

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 1 week. Please check your data on the server as soon as possible after it is acquired.

Reporting of an Adverse Event

Investigators whose IRB-approved studies utilize UR CABIN resources should follow the reporting policies of the Research Subject Review Board (RSRB). Investigators should also notify the UR CABIN technologist, Renee Stowell (renee_stowell@urmc.rochester.edu) of any RSRB-reported Adverse Event/Unexpected Problem that has occurred during the use of UR CABIN facilities. Any RSRB-reported Adverse Event/Unexpected Problem that has involved UR CABIN procedures and may impact the safety of a research volunteer with future UR CABIN procedures (new implant found to be unsafe in the magnet, unsafe use of a device etc) needs to be reported to the UR CABIN. The UR CABIN 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 UR CABIN office.