

UR CABIN

MRI Policies & Procedures

Safety 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 watching a video, reading the UR CABIN Policies & Procedures, UR CABIN MRI Safety Issues and 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 can be found 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 your study subjects to ensure they will be safe to scan. The prescreening process will eliminate those people with an unsafe item without wasting a scanning slot. Any implants or devices used in the study must be reviewed and approved by the MRI Physicist (Edmund Kwok Edmund_Kwok@URMC.Rochester.edu or Madalina Tivarus madalina_tivarus@urmc.rochester.edu) and/or the MRI lead technologist (Pam Zachary Pamela_Zachary@URMC.Rochester.edu) prior to the scan day.

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. Usually, a patient will be given a card after the device is surgically implanted that shows the device manufacturer, model name, model number, whether it is safe for MRI and under what conditions, e.g., not exceeding certain field strength. If the implant card is not available, the operational note may sometimes provide the needed information. 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.

There are titanium aneurysm clips that are safe in a 3T MRI but we **do not** scan them **at the UR CABIN**. **ALL** aneurysm clips, and implants that require a power source to function, e.g., pacemakers and implanted cardiac defibrillators (ICD) are **contraindicated** for a scan at this facility.

If the subject has worked in a metal shop, they will need to take an orbital x-ray and show the radiologist's report to confirm there are no metal fragments inside the eyes.

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 CABIN staff and update your screening form.

Equipment owned by Researchers

All equipment owned by the researchers and used inside the magnet room must be checked and approved by UR CABIN before the study begins.

People in the Control Room

Only personnel associated with the ongoing study will be allowed in the control room at that given time. In other words, if there is a study in progress that you are not a part of, you cannot enter the control room. If you are running studies back-to-back you cannot 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 parents, 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. 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 them to the MR technologist; (2) explain to the subjects what will be required from them as being part of the study; (3) confirm with the MR technologist the protocol to be acquired; (4) provide help and follow directions of the MR technologist 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 their 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.

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 **UR CABIN 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 or any raw images to a study subject.

The policy of the center is to release only one slice view extracted from the imaging data. All metadata must be removed, any PII or PHI that is 'burned in' must be irreversibly blacked out.

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 should book a 60 min scanning slot. You must be leaving the control room (not the scan room) at the end of your reservation time.

If for any reason we are not be able to finish your study within your reserved time, you will have to reschedule. This also applies if you/your subject are late for your reserved time. We want to be respectful of everyone's booked time and cannot delay the start of the study scheduled after yours.

To keep scheduling fair only reserve time on the calendar when you 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.

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 for time that you need. If your subject cancels, please be mindful to other users and take the time off the calendar.

There are other assessment rooms available for booking as a resource on the calendar if you need to administer tests before or after the MRI session.

Incidental Findings

If the MR technologist observes an unexpected abnormality in the images, the images will be sent to a radiologist for a review. The radiologist will email the study PI about the findings. It is the responsibility of the PI to notify the subject of the abnormality.

Data Storage

The images are transferred to CABIN servers immediately after the scan. The images remain on the scanner console for one week, after which they are removed. Please check you have ALL your data on our server after each scan to avoid losing it.

The University requires all data to be stored in at least one of these following secured environments, these include the cost of management and backups.

- SMDNAS based data storage (\$200/TB/year)
- CIRC Data Storage (\$299/TB/year)
- ISD Shared File Services (\$500/TB/year)

If your lab does not already have a space, an area on SMDNAS will be reserved. The cost for your storage must be included in your budget (most scanning protocols collect 2-4GB of raw data per hour). You may use the same storage for lab use and analysis, although you will need to budget for that space usage accordingly.

We will not provide your data on ANY portable media (eg. CD or USB drive) or ANY service not contracted with through the University (eg. cloud storage). If you need to share data outside the URM or use a third party service, please contact the IRB for a data use/sharing agreement (DUA) and/or HIPAA business associate agreements (BAA).

If you are unsure what data storage to use or for options to share your data outside the URM, send an email to [Helpdesk CABIN MRI@rochester.edu](mailto:Helpdesk_CABIN_MRI@rochester.edu). The PI of a study is responsible to adhere to all policies, laws and regulations governing the proper storage, sharing, unauthorized access, loss, or theft of your data.

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). Any RSRB-reported Adverse Event/Unexpected Problem that has involved UR CABIN procedures 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.

Any exceptions to these policies must have prior approval of one of the CABIN directors.