Center for Brain, Biology & Behavior

Magnetic Resonance Imaging (MRI) Facility
Standard Operating Procedures

Last Revised: 06.19.18

Contents

Purpose

This Standard Operating Procedures (SOP) manual describes the basic steps involved and procedures to be followed for researchers who wish to access the Siemens Skyra 3.0 Tesla MRI scanner in the Center for Brain, Biology & Behavior (CB3) at the University of Nebraska-Lincoln. Specifically, the manual covers the levels of access to the MRI Facility; safety screening and training required to gain access; and policies and procedures for conducting research with human subjects in the facility. This manual is made available on the CB3 MRI website and to those conducting research using the MRI through the MRI Users Box folder. The manual is maintained in NUgrant and will be reviewed annually or more often if significant changes are needed.

CB3 MRI Facility Zones and Levels of Access

The CB3 MRI Facility is mapped out in four different zones. Each of these zones is defined with respect to the possible safety hazards in reference to the MRI equipment, with Zone 1 being the least dangerous (no known hazards) and Zone 4 being the most hazardous. Below the four zones are depicted and described.

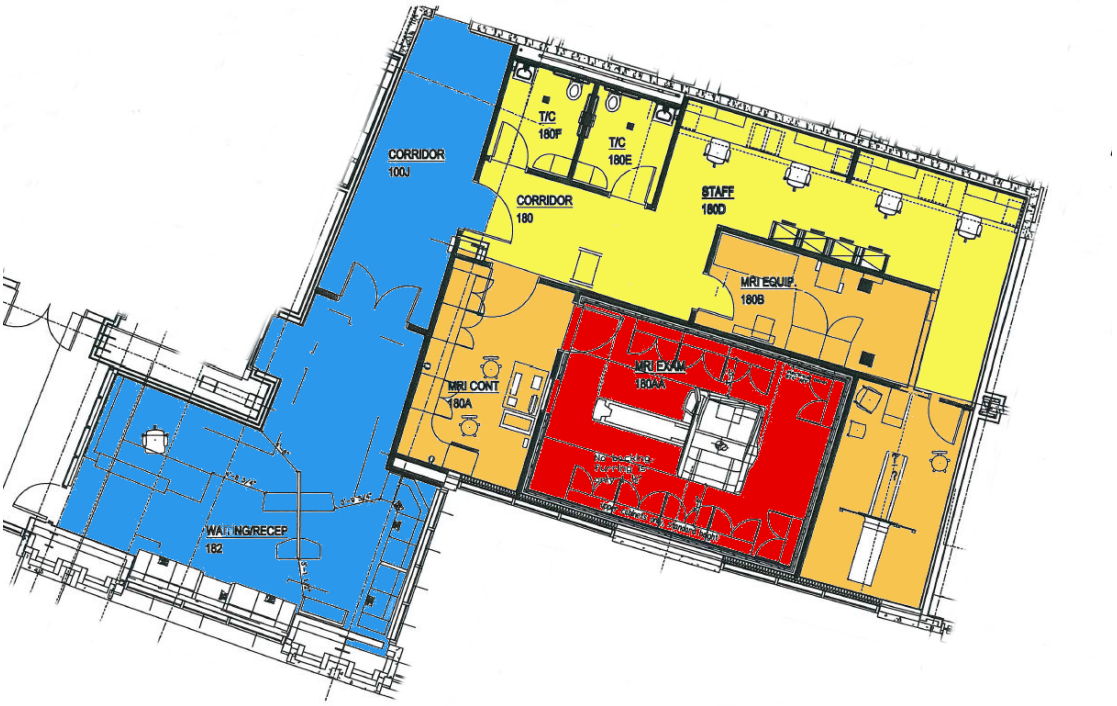

Fig. 1. *Blueprint of CB3 MRI Facility. Zones are color coded. Zones 2-4 are referred to as the MRI Suite.*

Zone 1

Zone 2

Zone 3

Zone 4

Zone Descriptions

Zone 1 – *(Reception area)*
This region includes all areas freely accessible to the general public from 8:00 am – 5:00 pm on business days. All other hours require CB3 building card access. There are no magnetic fringe fields in this zone.

Zone 2 – *(Common area within MRI Suite)*
This region is the interface between the publicly accessible Zone 1 and the strictly controlled Zone 3. Typically, research participants are greeted in Zone 1 and are under the supervision of MRI and research personnel in Zones 2-4. This zone is restricted by pin and card access. There is a small magnetic fringe field from 0.05mT to 0.2mT that registers within this zone.

Zone 3 – *(Control, Simulator, and Equipment Rooms)*
This zone is restricted by additional card access beyond the Zone 2 pin and card access entry point. Zone 3 can contain a magnetic fringe field as little as a 0.05mT and as much as 0.5mT depending on location within the room. *(Examples of devices affected include: pacemakers, insulin pumps, shunts, aneurysm clips).*

Zone 4 – *(MRI Room)*
The MRI scanner room is restricted by additional key to which only Level 2 MRI personnel (MRI Technologists) have independent access. Any other personnel (e.g., members of research teams) should be accompanied by (or under the immediate supervision of and in visual contact with) Level 2 MRI personnel for the entirety of time they are in Zone 4. This zone contains a magnetic fringe field as little as 0.5mT up to 3.0T.

Levels of Personnel Access

Level 1 MRI Personnel – No MRI Suite Card Access. Individuals with Level 1 access include those who require access to Zones 2-3 of the MRI Suite to conduct research or perform their job duties (in the case of staff). These individuals complete safety training with the MRI Technologist to ensure their own safety as they work within the MRI Suite. With the exceptions of UNL CB3 resident faculty conducting MRI research, UNL CB3 affiliated faculty with MRI expertise conducting MRI research, and researchers needing access to the MRI Simulator for sessions with participants, all other researchers are Level 1 MRI personnel, who do not have MRI Suite card access but may enter the suite when accompanied by the MRI Technologist and/or their faculty supervisor.

Level 1 MRI Personnel – MRI Suite Card Access to Zones 2-3. Per the CB3 MRI Suite Card Access Policy, designated Level 1 MRI Personnel are granted card access to Zones 2-3. These personnel include designated CB3 staff, CB3 resident faculty conducting MRI research, UNL CB3 affiliated faculty with MRI expertise conducting MRI research, Cassling service technicians, and University Police. Note researchers requiring access to the MRI Simulator to conduct sessions with research participants are granted MRI Suite and Simulator Room access (as the MRI Technologist is typically not involved in MRI Simulator sessions). Other Level 1 Personnel may accompany those with card access into Zones 2-3 as long as those with card access verify that anyone accompanying them has completed the necessary safety screening and training required for Level 1 status (see next section).

Level 2 MRI Personnel – MRI Suite Card and Key Access to Zones 2-4. Individuals with Level 2 access include those who have key access to the Zone 4 MRI Room, in addition to card access to the MRI Suite. These individuals have been more extensively trained and educated in the broader aspects of MRI safety, in most cases to the level that they are able to independently operate the MRI scanner. As of now, the MRI Technologists are the only personnel at CB3 having completed this level of training. Others granted Zone 4 key access include Cassling service technicians.

Restricted Personnel. Participants and visitors, as well as faculty, staff, and students who do not meet criteria for Level 1 or Level 2 MRI Personnel, are restricted access to Zones 2-4. They may only be escorted within Zones 2-4 by Level 1 or Level 2 Personnel with card access, pending any safety screening.

Researcher Safety Screening and Safety Training

All persons, including faculty, staff, and students, who require access to the MRI Suite are required to complete and maintain an updated MRI Safety Screening form on file in the MRI Facility. Additionally, these persons are required to complete the MRI Facility safety training curriculum. These requirements are to ensure that all persons accessing the MRI Facility meet the personal health requirements for safe entry and that they are trained in how to safely behave in the MRI environment. The MRI Safety Screening form and safety training ***must*** be completed ***prior*** to MRI Suite access being granted.

Researcher Safety Screening

MRI Safety Screening forms may be obtained on the CB3 MRI website at http://cb3.unl.edu/mri/ or from the MRI Facility receptionist, either at mri@unl.edu or in person in the lobby of CB3. Each person is required to meet briefly with the MRI Technologist to review the completed form before the signature of the MRI Technologist indicates the person is approved from a personal health standpoint for entry into the MRI Suite. Safety screening forms for faculty, staff, and students are required to be updated every 2 years, or sooner if there is a change in health status. ***Such changes to personal health that may affect MRI Suite access eligibility must be reported to the MRI Technologist immediately for review.*** MRI Safety Screening forms are stored electronically on a secure server, with access granted only to designated CB3 staff. Original hard copy forms are shredded after scanned. Electronic forms are stored for the duration of the relationship with CB3.

Safety Training

Training in the safety considerations when working and conducting research in the MRI environment is offered in the form of an in-person group class with the MRI Technologist. The 1.5-hour training class consists of a video, lecture, quiz, and MRI Suite tour. Safety training is currently offered on an "as needed" basis. Please contact the MRI Facility receptionist in the lobby of CB3 or by email at mri@unl.edu to register for a safety training class.

Policies and Procedures for Conducting Human Subjects Research

Upon completion of safety screening and safety training, researchers are granted Level 1 status and are approved for access to the MRI Facility to conduct research. The below details policies and procedures related to the steps involved in conducting a research project in the facility.

1. MRI Facility Project Approval Form

Researchers interested in conducting a research project in the MRI Facility should complete a project approval form to provide basic information about the project (see Appendix A). The form will be reviewed by CB3 Administrators. This approval process ensures that the MRI Facility can accommodate the proposed project time line and targeted number of participants prior to PIs beginning a project.

2. IRB Approval and CITI Training

Before conducting any research with human subjects, your project must be approved by the University of Nebraska-Lincoln Institutional Review Board (IRB). Please visit http://research.unl.edu/researchcompliance/human-subjects-research/ to learn more about the process of

applying for UNL IRB approval. The MRI Facility has developed UNL IRB-approved standard consent form language, including a policy and language for incidental findings. These documents are available via a shared Box folder for MRI Facility researchers. Please contact Jennifer Nelson at jnelson18@unl.edu to gain access to this Box. ***Investigators are strongly encouraged to use the standard language when submitting IRB projects involving MRI/fMRI, EEG, eye tracking, and/or physiological recordings within the CB3 MRI Facility.***

Regarding the policy and language for incidental findings, note images are only provided to research participants in cases when the consulting neuroradiologist identifies an abnormality that warrants medical follow-up. ***Images are otherwise not to be provided to research participants, unless a researcher seeks and receives IRB approval within his or her specific IRB project protocol to share images more broadly.***

Upon receiving IRB approval, please provide the MRI Facility receptionist with a copy of your letter of approval and a PDF of the NUgrant project summary, which includes the list of project personnel with proper CITI training to assist with the project. Updated letters of approval should be provided to the MRI Facility annually at the time of continuing review for projects exceeding one year. An updated project summary should be provided to the MRI Facility when changes occur, so the facility retains documentation of IRB-approved project personnel for each project.

Checklist: Beginning a New Research Project in the MRI Facility	
✓	Project Approval Form
✓	Safety Screening
✓	Safety Training
✓	UNL IRB Approval
✓	Submit IRB approval letter and PDF of NUgrant project summary to MRI Facility
✓	Begin data collection!

Note: To most efficiently begin a research project in the facility, new investigators are encouraged to enroll in a safety training class early in the process. This way **work on study design and set-up in the MRI Suite can begin while investigators are seeking project IRB approval**, enabling them to begin the project upon receiving IRB approval.

3. Participant Recruitment, Scheduling, Billing, and Safety Screening

Participant Recruitment

The PI and research team for each project are responsible for participant recruitment for the project following the IRB-approved recruitment protocol.

Scheduling and Billing

The PI and research team are required to schedule time for research or work in the Control/MRI Rooms and in the MRI Simulator Room ahead of time by consulting the MRI Facility receptionist in the lobby of CB3 or at mri@unl.edu, or by viewing the electronic MRI calendars. Scheduling occurs on a first-come, first-served basis.

Outlook MRI Suite calendars are used for scheduling (one for the MRI, and one for the MRI simulator – time in the MRI Simulator Room is not billed). The MRI calendar indicates at the top of each day the times that the MRI Suite is available for scheduling based on MRI Technologist availability. All researchers with projects approved to occur in the MRI Facility are granted read and write access to these calendars if they wish, so they are able to view the calendars and schedule events as needed. Please request access to the calendars by contacting the MRI Facility receptionist at mri@unl.edu. Details regarding the information required when placing an event on the calendar are found in the calendar guidelines for scheduling a new appointment (see Appendix B).

As noted in the calendar guidelines, there are several **policies related to scheduling time and billing** in the MRI Suite. Scheduled time must include all time the MRI Zones 3 and 4 Control and MRI Rooms will be occupied and/or the MRI Technologist will be required by the research team and participant (not to include time completing paperwork with the research team ahead of data collection nor time for the participant to change clothes). Reserved time should be scheduled and will be billed in 15-minute increments, with a minimum of 30 minutes scheduled and billed per reservation/data collection session. Unused fractions of the first 30 minutes or 15-minute increments thereafter cannot be carried over to a future scheduled event. A 15-minute break should be left on the scheduling calendar between scheduled events and at the beginning and end of the time the MRI Technologist is available on any given day.

Scan sessions must begin and end on time according to how they are scheduled on the calendar. PIs/research teams are encouraged to have participants arrive early enough to complete all paperwork, behavioral testing, or other parts of the research protocol in plenty of time before the scheduled scan time. Likewise, research teams should plan to end on time, allowing time at the end of the session for any clean-up and data archiving that must occur within the MRI Suite or involve the MRI Technologist. If you are running late, you risk being unable to complete data collection as the MRI Technologist will need to stop the procedure in time for the next scheduled PI/research team time. Any overage in session time will be billed by the quarter hour.

The types of events that can be scheduled in the MRI Suite are detailed in the calendar guidelines. As of now, the **billable events** are Protocol Tests with Subjects and all Research Participant sessions. Billing will occur at the University approved rate; for current rates please contact Jennifer Nelson at jnelson18@unl.edu. Each PI/research team is allowed three hours of non-billable Protocol Tests with Subjects (not to exceed $1,755 in total cost if billable) per approved project before these become billable per project. Other work in the suite, including protocol creation and equipment tests, are not billed, though it is ideal for this type of work to occur at down times in the MRI Suite so as to not detract from the availability of time for research participants.

It is ideal for events to be **scheduled at least 24 hours in advance** to ensure that any on-call MRI Technologists are aware of the need to report to work. However, if it is confirmed that MRI Technologist coverage is available (when needed), events may be scheduled with shorter notice.

The **current cancellation policy** is such that it is preferred that reservations be modified or canceled no later than 24 hours prior to their start times. However, the MRI Facility does not currently bill canceled sessions even if they are canceled the day of the session. Please be aware that as the schedule becomes (mostly) full and making reservations becomes more difficult, research reservations canceled within 24 hours will likely be billed, as these cancellations may have prevented another research team from scheduling a participant. ***Please note that sessions in which participants arrive but are deemed by the MRI Technologist during safety screening as unsafe to enter the MRI Suite will be billed (see next section).***

Every effort will be made to avoid **MRI Facility initiated schedule changes**, but staffing or equipment problems may lead to unavoidable rescheduling. The PI/research team will be notified as soon as possible if a scan must be rescheduled. Such interruptions of services are not charged against the PI/research team.

Please note that scheduling and billing policies are subject to change as there is more demand on the MRI Facility and the MRI Technologist time.

Participant Consent and Safety Screening

As with any research project, research participants must **consent/assent** to participate in research studies conducted in the MRI Facility. The PI/research team is responsible for executing the project IRB-approved consent/assent process, which must be completed prior to a scheduled scan.

Research participants must also complete a **MRI Safety Screening form** and meet with the MRI Technologist to review the form prior to a MRI scan. For youth research participants ages 13-18 years, a **MRI Safety Screening form for Youth** is also required, to gather youth self-report of some safety screening questions. The MRI Technologist is responsible for determining whether a participant is safe from a personal health standpoint for entry into the MRI Suite and participation in a scan.

Safety screening can be completed at the time of a scheduled research scan. However, PIs/research teams should be aware that ***if the MRI Technologist deems the participant to have unsafe implanted metal or other health-related contra-indications for a MRI scan, the session must be canceled, and the PI will be charged*** for the time slot. It is recommended that PIs/research teams ask basic prescreening questions during the recruitment process to reduce the likelihood of a canceled scan for safety screening reasons. Alternatively, if a PI/research team wishes to consent research participants and request their return of a Safety Screening form in advance of a scheduled scan, the MRI Technologist can work with research teams to review forms and seek any needed additional information regarding participant health in advance.

Note that for studies involving children, parents or guardians may be required to complete a MRI Safety Screening form themselves, depending how present they wish to be in the MRI Suite during the research scan.

All research participant Safety Screening information will be stored electronically in the CB3 MRI Facility for 3 years after the conclusion of the associated research project. Information will be scanned on a password-protected scanner and automatically transferred to a secure server. All hard copies of information will be shredded upon scanning.

Note about Test Scan Subjects versus Research Participants

It is important to note the differences between test scan subjects and research participants:

- **Test scan subjects** participate in MRI scans to assist the research team in testing and confirming MRI protocols and procedures the team intends to use during a research project. Test scan subjects are required to complete the MRI Safety Screening form but are not required to provide legally effective informed consent/assent.
- **Research participants** are involved in research projects, meaning informed consent/assent is required, as is the MRI Safety Screening form.

Note that the term **"pilot"** is sometimes used synonymously with test scan subjects, and other times used synonymously with research participants (as defined here). ***If a pilot is conducted with the possible***

intention of using the information collected for research purposes, the piloting process must be IRB-approved and include an informed consent/assent procedure.

Even though test scan subjects are not required to provide research consent/assent, the CB3 MRI Facility believes it is still important that test subjects are fully informed of the general risks of MRI/fMRI and of the specifics of the scan for which they are invited to serve as a test subject. Therefore, PIs/research teams conducting MRI protocol tests with subjects are required to review the **Test Scan Subject Form** (see Appendix C) with any test subjects, and invite them to sign indicating their understanding and agreement to participate. **For each PI, one signed form is required on file from each person who agrees to serve as a test scan subject for research projects conducted by that PI.** While it is the responsibility of the PI/research team that these are completed, the MRI Facility will store electronic copies of the forms. PIs/research teams may also retain copies of the signed forms for their records if they wish.

4. Data Collection

The following details components of the MRI data collection process, with a focus on distinguishing responsibility between the MRI Technologist and the PI/research team. As a rule of thumb, the MRI Technologist is responsible for the safety of the research participant and the MRI environment in general, and for the operation of the MRI scanner. The PI/research team is responsible for all other aspects of the research session, including explaining any research procedures to the participant, specifying the MRI protocol, and running any ancillary equipment.

Prior to Scheduled Data Collection

The PI/research team is responsible for making sure the MRI sequences and protocols are set up and clearly specified, so the MRI Technologist is clear which sequences and protocols to run when a research project data collection session occurs. The CB3 Specialized Technology Manager is tasked with maintenance of the MRI Suite ancillary equipment (e.g., stimulus delivery computer and software, button box, EEG/ERP equipment, eyetracker), to ensure it is in good operating order at all times, and any needed supplies are available. The PI/research team is responsible for making sure any stimulus delivery programs are ready prior to a data collection session.

Data Collection Procedures

The below specifies the order of activities and division of responsibilities during a data collection session:

1. The PI/research team member(s) ensure they have removed any metal from themselves, including checking pockets, in order to be prepared for the MRI data collection session.
2. The PI/research team member(s) greet participants in the lobby of CB3, guide participants through the completion of any paperwork or other parts of the research protocol, and escort them back to the MRI Suite when ready.
3. The MRI Technologist reviews the MRI Safety Screening form with the participant.
4. The participant changes into scrubs, including removing shoes (and attaches electrocardiogram (ECG) leads to their upper torso if needed). Instructions are posted within each changing room.

   (Steps 4-6 may occur in any order.)

5. The PI/research team member(s) provide the participant any instructions regarding the research procedures during the MRI scan.
6. If the participant's glasses are not deemed to be MRI safe, the PI/research team member(s) help the participant find the correct lenses from the MRI-safe lenses set.
7. If simultaneous EEG will occur, the PI/research team member(s) ensure the net is properly placed and impedances checked.
8. Earplugs are provided to the participant and inserted either by the participant or the MRI Technologist.

9. The MRI Technologist escorts the participant and the PI/research team member(s) (if they need to enter) into the MRI Room. ***All individuals entering the MRI Room must be accompanied by (or under the immediate supervision of and in visual contact with) the MRI Technologist.***
10. The MRI Technologist positions the participant on the table, gives the participant the squeeze bulb to enable communication with the MRI Technologist during the scan, and provides any instructions about use of the squeeze bulb.
11. The PI/research team member(s) provide any last instructions regarding the research procedures that need to be provided in the MRI Room as opposed to prior to entry.
12. The MRI Technologist secures all cables and is the ***last person out of the MRI Room***.
13. The MRI scan is conducted.
14. When data collection is complete, the MRI Technologist escorts the participant out of the MRI Room.
15. The participant changes back to original dress, and the PI/research team member(s) escort the participant out of the MRI Suite.
16. Per the details below, the PI/research team member(s) collect any ancillary data to take with them from the MRI Suite. The PI/research team member(s) assist the MRI Technologist in any clean-up related to the session in the Control Room or other areas of the MRI Suite to ensure the area is clean for the next scheduled scan.

Note that for safety reasons, anytime the MRI Room door is open, the Control Room door must be closed.

Specific Responsibilities of the MRI Technologist During a MRI Scan

1. Inform the participant that peripheral nerve stimulation may occur, and describe the nature of the sensation.
2. Instruct participants not to clasp their hands, cross their legs, or otherwise create a conductive loop that can increase the possibility of stimulation and RF burns in the MRI machine.
3. Ensure that cables from all devices (e.g., EEG net, response boxes, etc) do not touch the participant or form a loop within the bore of the MRI machine at any time.
4. Ensure that the participant's anatomy is shielded from the bore walls and/or cables by blankets or sponges throughout the entire exam.
5. Instruct the participant regarding the proper use of ear plugs to prevent acoustic noise issues.
6. Maintain continuous visual and verbal contact with the subject (e.g., squeeze ball or intercom).
7. Instruct the participant to inform the operator if they experience discomfort.
8. Terminate the scan if the participant complains of discomfort, pain or fear.
9. Complete a report of any incidents involving severe discomfort or pain.

MRI Technologist Documentation of the MRI Scan

Each time a MRI scan is conducted with an individual (protocol test scan subject or research participant), the MRI Technologist completes a CB3 MRI Facility Scan Information Sheet (see Appendix D) to document the scan. The sheet includes the unique sequential MRI Facility code assigned to each scan session, as well as the PI name, research project name (matching NUgrant project name for scans conducted for research purposes), MRI Technologist name, duration of time the participant and PI/research team were in the MRI Suite, duration of the scan, and any participant or technical issues that resulted in the MRI scan not being completed. Completed information sheets are stored in a binder in the MRI Suite Control Room and will be scanned to the MRI Facility server partition for longer-term storage, with access only to designated CB3 staff.

5. Server Access and Data Retrieval

All scans are immediately exported from the MRI control computer to a PACS management server where scans are stored in PI specific folders. These folders can only be accessed by the PI. The file placed into the individual PI folder is a copy of the original scan file that the PI can download and manipulate. The original scan file is housed as a temporary back-up in a server folder that individual PIs cannot access. Since this back-

up cannot be stored indefinitely on the PACS server, PIs should download their scans and utilize their own storage solutions. When the scan data file is moved from the MRI control computer to the PACS server, it maintains only a unique MRI suite code, which is wiped from the file once downloaded from the PACS server. The PACS server is protected by a dual firewall configuration and is housed behind a dual-lock door. New MRI PIs should see Noah Clayton (nclayton3@unl.edu, 472-3720) to arrange PACS server access.

PIs/research teams utilizing ePrime, Net Station or the SR Research eye tracker should be aware that none of these files are transferred automatically to the PACS server. PIs/research teams should always save these data files on an external hard drive, flash drive or CD/DVD prior to leaving the MRI Suite after data collection.

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