SOP 202: Zone Access

1 Summary

This document establishes MRI Safety Zones of the research suite at the Notre Dame Human Neuroimaging Center (ND-HNC). These Zones follow the American College of Radiology guidelines and are designed to ensure that Zone access is commensurate with training and experience. Roles and restrictions for each level of access are also described.

2 Scope

These policies apply to all investigators, research assistants, and ND-HNC staff who enter Zones 3 & 4 (B15, B17, B17a; Fig. 1).

3 Definitions

- **DICOM Computer**: The Mac Studio located in the Control Room the receives DICOM files from the scanner.
- **Control Room**: B17; The main room of the MRI suite that contains the computer displays and keyboards that control the MRI scanner. The Control Room is accessed from B15 that is controlled by an Electronic Lock.
- **EEG**: Electroencephalograpy, a technique used to measure changes in electromagnetic properties of neural tissue.
- **Electronic Lock**: All doors at the ND-HNC are controlled by electronic locks. The electronic lock system recognizes the owner's Irish1Card, logs the time of the attempted entry, and unlocks the door if the owner has been granted access.
- **Magnet Room**: B17A; The room within the MRI suite that contains the MRI scanner. It is accessed from within the MRI Control room (B17) through a doorway that is controlled by an Electronic Lock.
- **Stimulus Control Computer**: The Windows machines in the Control Room that deploy fMRI tasks and capture participant responses.
- **Supervision**: A supervisor is continuously present in both sight and sound range of the individual or task being monitored. This approach ensures the supervisor can actively observe, direct, and immediately intervene if a complication or safety issue arises.

- **TMS**: Transcranial magnetic stimulation, a technique used to disrupt normal operations of neural tissue.
- **Visitor**: An individual who has not taken the ND-HNC MRI Safety Course but has a legitimate reason for entering the MRI suites. Research participants and their legal guardians are Visitors. Other Visitors may include: individuals providing/receiving a tour of the VFPC and ND-HNC, faculty and staff who have not received MRI Safety Course, and research assistants.

4 Notes

1. The MRI simulator (mock) is **NOT** compatible with pacemakers!

5 Policies & Procedures

In the sections below Safety Zones, user access, and user responsibilities are described.

5.1 Research Suite

The ND-HNC research suite consists of the following rooms and areas (see Fig. 1):

1. Reception (B04)
2. Staff offices (B28, B32, B34)
3. Data processing and conference (B30, B26)
4. Interview and changing (B05-06, B10-11)
5. EEG: preparation, testing, and control (B19-22)
6. TMS: administration (B23)
7. MRI: simulator (B14)
8. MRI: vestibule, equipment, control (B15, B17-18)
9. MRI: magnet room (B17a)

These are located on the lower level of the Veldman Family Psychology Clinic. See SOP 301 for access procedures.

5.2 Safety Zones

The research suite is organized into four Safety Zones (Figs. 1, 2). See section 5.3 for description of Access Levels.

5.2.1 Zone 1

This area constitutes the reception area, staff offices, conference room, and data processing room (5.1, 1-3). The reception area is accessible from the building's main reception and is used as a waiting area for researchers and Visitors. A bathroom and consultation rooms are accessible from the waiting area. The staff offices, conference room, and data processing room are accessible from the staff entrance and are used for ND-HNC related administration, research, and meetings. A break room and staff bathroom are also located in this zone.

MRI Safety screening (see SOP 201) is **NOT** required for entry into Zone 1. This is typically the zone where such screening is conducted.

5.2.2 Zone 2

This area consists of changing rooms, a bathroom and shower, interview rooms, MRI simulator, EEG, and TMS rooms (5.1, 4-7). Zone 2 is accessed from Zone 1 with the Irish1Card. Zone 2 is used for research protocols that do not involve the MRI machine (e.g. behavioral testing, clinical assessment, EEG, and TMS). MRI Safety screening can be conducted in Zone 2 but is typically done in Zone 1. Visitors must be escorted in this Zone by a researcher with at least Level 1 access.

MRI Safety screening (see SOP 201) is **NOT** required for entry into Zone 2 when the Visitor will not contribute MRI data.

5.2.3 Zone 3

This area consists of the MRI vestibule, equipment, and control rooms (5.1, 8). Zone 3 is accessed from Zone 2 with the Irish1Card. This area is used for collecting MRI data and maintaining MR-related hardware. Researchers with Level 2 access can enter this area for MRI-related purposes when supervised, and Visitors must be escorted by a researcher with at least Level 3 access.

MRI Safety screening **IS** required for entry into Zone 3, and Form RO01: MRI Safety Screen must have been reviewed and approved by a researcher with at least Level 2 access (see SOP 201).

5.2.4 Zone 4

This area consists of the Magnet Room (5.1, 9), where the MRI machine is located. Zone 4 is accessed from the Control Room (Zone 3). Researchers with Level 3 access may enter this zone with permission, and must be supervised by the MRI Technologist or a researcher with Level 4 access.

MRI Safety screening **IS** required for entrance into Zone 4, and this screening must have

been reviewed and approved by the MRI Technologist or a researcher with Level 4 access (in addition to the Level 2-3 approval noted above, see SOP 201).

5.3 Access Levels

Access to the ND-HNC research suite is restricted to research personnel and Visitors. Anyone with building access is able to visit Zone 1. Access to additional Zones requires a demonstrated and current need as well as additional training and certifications.

5.3.1 Level 1

Level 1 researchers may enter Zone 2 in order to access the interview, EEG, and TMS rooms. They escort Visitors in these areas. Their level of access relates to non-MRI activities.

Requirements:

- Complete annual ND-HNC MRI Safety training.
- Participate in building access and safety trainings (SOP 300s).
- Wear Level 1 access badge while in the ND-HNC research suite.

Recommendations:

- Complete first-aid and CPR training.

Privileges:

- Unsupervised access to Zone 2.
- Escort Visitors in Zone 2.

Restrictions:

- No access to Mock Room (B14).
- No access to Zone 3 (B15, B17, B18).
- No access to Zone 4 (B17a).
- Cannot review Form RO01: MRI Safety Screen.

5.3.2 Level 2

Level 2 researchers may enter Zone 3, under the supervision of a researcher with at least Level 3 access, to assist in MRI-related research activities; they have access to the Stimulus Control and DICOM computers. They may also enter Zone 4 under the supervision of the MRI Technologist or a researcher with Level 4 access. Level 2 researchers have unsupervised access to the Mock room and can review and sign Form RO01: MRI Safety Screen. Level 2

researchers are undergraduate and graduate students and other research staff; most research assistants in the MRI suite are Level 2.

Requirements:

- Complete annual ND-HNC MRI Safety training.
- Maintain current first-aid and CPR training certifications.
- Annually provide Form RO01: MRI Safety Screen.
- Participate in regular refresher trainings.
- Wear Level 2 access badge while in the ND-HNC research suite.

Privileges:

- All Level 1 privileges.
- Access and use of Mock Scanner and Mock computer.
- Supervised access to Zones 3 & 4.
- Access and use of Stimulus Control and DICOM computers.
- Review and sign Form RO01: MRI Safety Screen.
- Help un/load Visitors into the MRI scanner.
- Can be the Helper in Emergency Responses (see SOP 100s).

Restrictions:

- No access to Zone 3 Equipment Room.
- Irish1Card access to Zone 3 is not granted.

5.3.3 Level 3

Level 3 researchers are more independent in Zone 3 and may access Zone 4 when supervised by the MRI Technologist or a researcher with Level 4 access. They are post-baccalaureate research staff, graduate students, post-doctoral fellows, and faculty. They are typically the Helper in Emergency SOPs but can be the Lead when they are the researcher with the highest level of access. Level 3 researchers may train to become an MRI operator (Level 4) for project-specific reasons (e.g. weekend pediatric scanning).

Requirements:

- Complete annual ND-HNC MRI Safety training.
- Maintain current first-aid and CPR training certifications.

- Annually provide Form RO01: MRI Safety Screen.
- Pass Emergency SOP exam.
- Participate in regular refresher trainings.
- Wear Level 3 access badge while in the ND-HNC research suite.
- Current Notre Dame graduate student, post-doctoral fellow, or faculty.
- Complete 30 hours of research assistance in Zone 3 as Level 2 (record with Form LG05: Shadow Hours).

Privileges:

- All Level 2 privileges.
- May supervise Level 2.
- Unsupervised access to Zones 3.
- Supervised access to Zone 4.
- Can be the Helper or Lead in Emergency Responses (see SOP 100s).
- When training for Level 4 and supervised:
  - Access MRI Control computer.
  - Operate the MRI scanner.
  - Perform start-up/shutdown procedures.
  - Perform QA/QC.
  - Access MRI Equipment room.

Restrictions:

- No unsupervised access to Zone 4.
- Cannot be second reviewer of Form RO01: MRI Safety Screen.

5.3.4 Level 4

Level 4 researchers are independent in the MRI research suite but operate under guidance and with permission from the MRI Technologist. They are the Lead in Emergency SOPs, and can be the second reviewer of Visitor Form RO01: MRI Safety Screen (but must not be the same person that performed the first review). They are Ph.D. candidates, post-doctoral fellows, and faculty.

Requirements:

- Complete annual ND-HNC MRI Safety training.
- Maintain current first-aid and CPR training certifications.
- Annually provide Form RO01: MRI Safety Screen.
- Pass operator exam.
- Pass emergency SOP exam.
- Participate in maintenance training.
- Wear Level 4 access badge while in the ND-HNC research suite.
- Current Notre Dame Ph.D. candidate, post-doctoral fellow, or faculty.
- Complete 30 hours of training as Level 3 (record with Form LG05: Shadow Hours).

Privileges:

- All Level 3 privileges.
- Unsupervised access to Zones 3 & 4.
- Lead in Emergency Responses (see SOP 100s).
- Independently perform:
  - Scan Visitors.
  - Start-up and shutdown procedures.
  - QA/QC scans.
  - Troubleshoot issues.
  - Maintain relevant logs.
- Coordinate with ND-HNC staff
- Train Levels 2-3.

Restrictions:

- Must be accompanied by a second person of at least Level 2 access when a Visitor is in Zone 4.
- Operates at the discretion of the MRI Technologist and other ND-HNC staff.

5.4 Staff Access

Staff employed by the ND-HNC have unsupervised access to the MRI suite (Zones 1-4), and access the Zones in order to fulfill their respective job responsibilities. They promote an environment of safety and accountability, enforce Standard Operating Policies, and report compliance issues. Staff maintain and participate in MRI Safety and SOP trainings, first-aid and CPR certifications, and submit Form RO01: MRI Safety Screen annually. In an emergency, they can assist as Lead or Helper. The Siemens Customer Service Engineer also has unsupervised access to Zones 1-4.

6 Figures

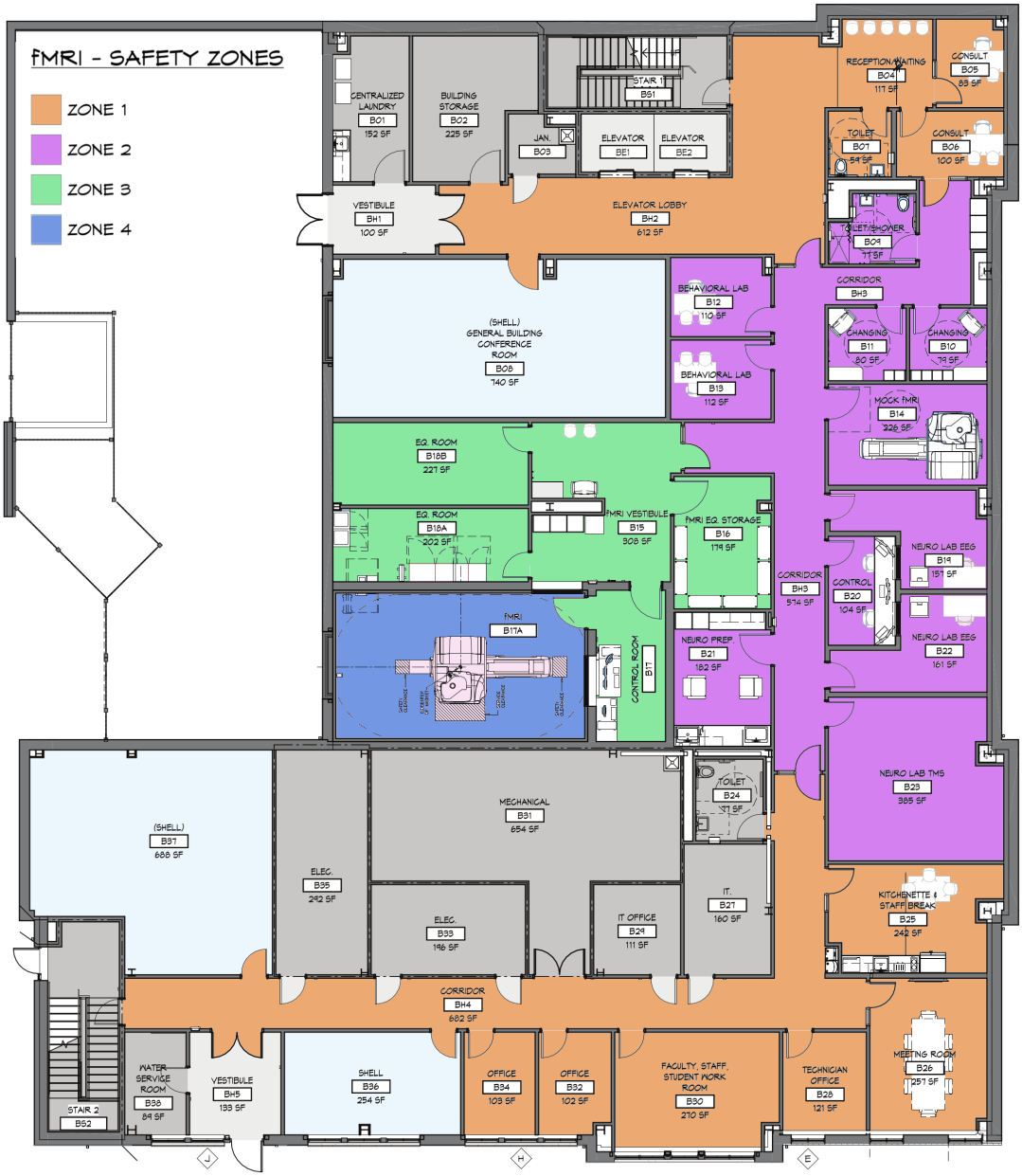

Figure 1: ND-HNC layout and MRI safety zones.

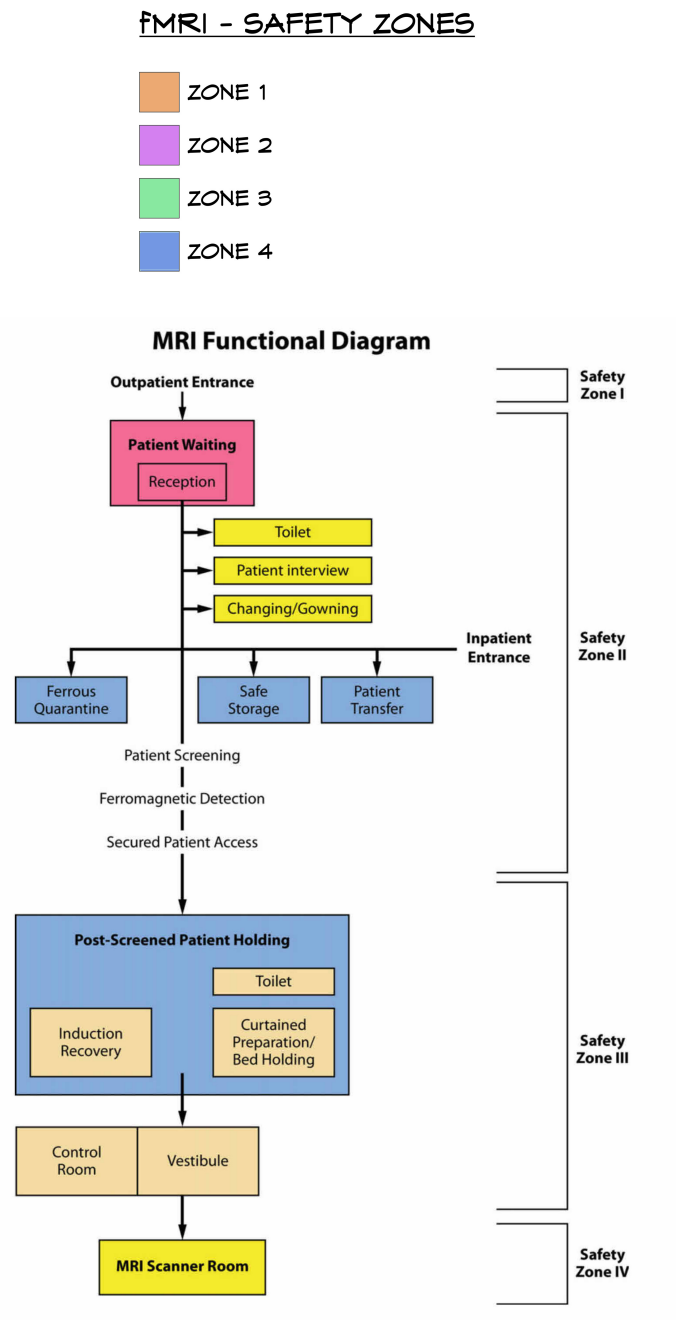

Figure 2: Diagram specifying MRI safety zones and their use.