

Policies and Procedures Manual

UNIVERSITY of CALIFORNIA SANTA BARBARA BRAIN IMAGING CENTER

Psychology East Basement

Room 0804

Prepared by BIC Staff and reviewed yearly by the start of Fall quarter

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Table of Contents

Section		Pages
1.	Research Protocol Requirements	3-5
2.	Clinical-Diagnostic Use Requirements	6-7
3.	Personnel Categories and Training Requirements	8-10
4.	Site Access and Restriction Policy	11-13
5.	MRI System Operation	14
6.	Emergency Response	15-16
7.	MRI Equipment Safety Inspection and Storage Policy	17
8.	Research Participant Screening and Safety Guidelines	18-21
9.	Personal Health and Safety Procedures in Response to Coronavirus (COVID-19) (2020-2021)	22-24
	Exhibit A: BIC Application Form	25-26
	Exhibit B: California Experimental Bill of Rights	27
	Exhibit C: Magnet Screening Form	28-29
	Exhibit D: Posters and Signage	30-34

SECTION 1: RESEARCH PROTOCOL REQUIREMENTS

This section establishes a set of criteria that UCSB-affiliated Principal Investigators must satisfy prior to conducting research activities using the Brain Imaging Center (BIC) resources. The BIC policies described below do not supersede established University policies and procedures developed by the IRB and IACUC.

Definitions:

PRINCIPAL INVESTIGATOR (PI): UCSB affiliated scientist or clinician with faculty rank of “researcher” or above. Post-doctoral fellows, medical fellows, graduate students, undergraduate students and staff cannot serve as a PI for a BIC project.

RESEARCH PROTOCOL: Set of documents related to the conduct of an experiment with humans, experimental animals, or materials.

Prospective researchers must submit application paperwork to the BIC for approval in addition to obtaining approval from the IRB or IACUC, as appropriate. To expedite review, application to the BIC and IRB can be made in tandem. All paperwork being submitted to the BIC should be submitted in electronic form (preferably in PDF format) to:

mghayes@psych.ucsb.edu

If needed, hard copy of any materials can be sent to:

UCSB Brain Imaging Center
Department of Psychological Brain Sciences
Building 251
UCSB
Santa Barbara, CA 93106

The application and approval process is as follows:

1. **BIC Application Form:** A completed application form (Exhibit A) must be submitted and approved by the BIC for each research project.

The BIC will not consider applications from those who are not a PI, as defined above.

Members of the UCSB community not holding faculty rank wishing to propose projects must arrange with an UCSB-affiliated faculty member to act as a sponsor to submit a proposal to the BIC. The identified faculty member must agree to assume responsibility for projects initiated by UCSB-affiliated individuals not holding faculty rank. The responsibility includes IRB submissions, supervision of research staff, and financial arrangements to use the BIC facilities.

Those outside the UCSB community wishing to conduct MRI research under the auspices of the BIC must enter into a collaborative relationship with an UCSB-affiliated faculty member. The identified UCSB faculty member must agree to assume responsibility for projects initiated by non-UCSB-affiliated individuals. The responsibilities include IRB submissions, supervision of research staff, and financial arrangements to use the BIC facilities.

2. **CV:** A CV for the PI must be submitted via E-mail to the BIC (PDF format).
3. **Research Project Description.** A completed research project description must be submitted via E-mail to the BIC (PDF format). The description should include pertinent details about the scientific aims of the project and the MRI-related software and hardware used in the conduct of the research.
4. **IRB Approval for Projects Involving Human Subjects:**

Information about the procedures and policies related to obtaining IRB approval for research projects conducted at UCSB appears at the web site of UCSB's Human Research Protections Office. <https://www.research.ucsb.edu/>

Projects cannot become initiated or continued without relevant IRB approval. PI's must provide written documentation of the initial IRB approval(s) and annual IRB renewal(s).

- a. All research projects involving human subjects must have approval of the UCSB IRB.
- b. Researchers based at non-UCSB affiliated institutions must obtain and submit approval forms from their home institutions as well as from the UCSB IRB. These individuals must have a formal collaboration with an UCSB-affiliated faculty member in order to conduct MRI research at UCSB.

5. IACUC Approval for Projects Involving Experimental Animals

- a. All research projects involving experimental animals are required to have the approval of the UCSB IACUC.
- b. Researchers based at non-UCSB affiliated institutions must obtain and submit approval forms from their home institutions as well as from the UCSB IACUC for the conduct of research using experimental animals. These individuals must have a formal collaboration with an UCSB-affiliated faculty member in order to conduct MRI research at UCSB.

6. Training Requirements

This section provides basic orientation to the training requirements. Section 2 and Section 9 have a more extensive treatment of training.

- a. MRI Safety Training. All individuals seeking access to the MRI facility to perform research or for educational activities must complete MRI safety training appropriate to their role in the work (see Section 2, Training Requirements, for details).
- b. Human Subjects Training. All researchers conducting human subjects research are required to complete training for research with human subjects (see Section 2, Training Requirements, for details). <http://hstraining.orca.ucsb.edu/IntroPage.htm>
- c. Experimental Animal Training. All researchers with a protocol that involves experimental animals are required to complete training for the proper use of experimental animals as specified in: http://research.ucsb.edu/iacuc/training_animal_users.shtml
- d. Emergency Procedures Training. For all protocols involving human subjects, at least two researchers must be present during each MRI data acquisition session, and at least one should have completed BIC emergency procedures training.

7. Insurance Requirements and Facilities Use Agreement for External Users:

- a. All non-UCSB employees must submit a completed UCSB Facility Use Agreement prior to using UCSB's MRI Facility. Non-UCSB employees include all researchers employed at non-UCSB institutions.
- b. The Facilities Use agreement must be signed by a person authorized to act on behalf of the researcher's institution.
- c. Insurance requirements and indemnification language will appear in the Facilities Use Agreement.
- d. Researchers wishing to obtain further information about the Use Agreement or insurance requirements should contact:

Katharine Hullinger
Risk Management and Insurance

565 Mesa Rd.
UCSB
Santa Barbara, CA 93106-2090
Business office
Email: katharinehullinger@ucsb.edu
Phone: 805-893-4169

8. Compliance.

The BIC Administrative Assistant, working with the Director, and MRI technologist will work with all researchers on ensuring that they comply with all matters pertaining to safety training, insurance, IRB and IACUC approvals and other items requiring paper documentation. All Principal Investigators have an obligation to adhere to IRB approved procedures for research protocols. The Staff Administrative Assistant will not schedule requests to use the MRI system until all approvals have been submitted and then maintained in good standing. The Staff Administrative Assistant will communicate with the staff operating the MRI system regarding the approval status of groups requesting instrument usage.

SECTION 2: CLINICAL-DIAGNOSTIC USE REQUIREMENTS

This section establishes a set of criteria that Clinical Diagnostic Radiologists must satisfy prior to renting the BIC resources. The BIC policies described below do not supersede established University policies and procedures. It is assumed that clinical-diagnostic use does not involve research and IRB approval is not required.

Definitions:

PRINCIPAL RADIOLOGIST (PR): Board certified radiologist with California medical license who is primary point of contact for a clinical-diagnostic group.

CLINICAL PROTOCOL: Use of the MRI scanner for clinical diagnostic purpose. There is no research component.

Radiologists must submit application paperwork to the BIC for approval. Materials can be sent to:

UCSB Brain Imaging Center
Department of Psychological and Brain Sciences
Building 251
UCSB
Santa Barbara, CA 93106

The application and approval process is as follows:

1. **BIC Application Form:** A completed application form (Exhibit A) must be submitted and approved by the BIC for each clinical group.
The BIC will not consider applications from those who are not a PR, as defined above.
2. **CV:** A CV for the Principal Radiologist must be submitted.
3. **Clinical Use Description.** A description of the types of imaging protocols to be performed on the 3T magnet should be provided. The description should include methods of patient monitoring, and use of gadolinium, sedatives and other medications.

4. Training Requirements

This section provides basic orientation to the training requirements. Section 2 and Section 9 have a more extensive treatment of training.

- a. MRI Safety Training. All individuals seeking access to the MRI facility to perform clinical procedures must complete MRI safety training appropriate to their role in the work (see Section 2, Training Requirements, for details).
 - b. Clinical Operations Training. All technologists performing clinical diagnostic imaging on patients are required to be board certified MRI radiology technologists, licensed in the state of California.
 - c. Emergency Procedures Training. All operators must have received emergency procedures training.
- ### 5. Insurance Requirements and Facilities Use Agreement for Clinical Users:
- a. All non-UCSB Clinical-Diagnostic users must submit a completed UCSB Facility Use Agreement prior to using UCSB's MRI Facility.
 - b. The Facilities Use agreement must be signed by a person authorized to act on behalf of the Clinical-Diagnostic entity.
 - c. Insurance requirements and indemnification language will appear in the Facilities Use Agreement.

- d. Clinical-Diagnostic operators wishing to obtain further information about the Use Agreement or insurance requirements should contact:

Katharine Hullinger
Risk Management and Insurance
565 Mesa Rd.
UCSB
Santa Barbara, CA 93106-2090
Business office
Email: katharinehullinger@ucsb.edu
Phone: 805-893-4169

6. Compliance.

The BIC Administrative Assistant, working with the Director will work with all clinical radiology groups to ensure that they comply with all matters pertaining to safety training, insurance and safe use of the facilities. The Clinical-Radiology operator will be fully responsible for providing an MRI technologist to perform clinical diagnostic studies, for patient scheduling, facility management during clinical hours, patient related paperwork, interpretation of MRI scans, data archiving and medical billing. BIC staff will be available to provide information on safety and facility operations, but will not perform the clinical diagnostic studies.

SECTION 3: PERSONNEL CATEGORIES AND TRAINING REQUIREMENTS

This section details policies and procedures ensure the safe operation of the MRI research facility, to protect volunteers, to protect research personnel and staff and to safeguard the BIC infrastructure.

See Section 9 for additional personnel categories and training requirements in response to Coronavirus (COVID-19) pandemic.

At the discretion of the BIC, Section 9 procedures will supersede Personnel Categories and training requirements as detailed in Section 3.

PERSONNEL CATEGORIES

The BIC has a categorical scheme for those who enter the MRI suite. The scheme has a hierarchical character with increasing levels of training and commensurate permission to use the facilities and facility equipment.

Volunteer: Individual who provides informed, written consent to participate in approved research protocols.

Patient: Individual who is examined by MRI for clinical diagnostic purposes.

Visitor: Individual without any or incomplete training related to MR safety, human subject participation or experimental animal research participation.

MRI-Researcher: Individuals who have passed safety and basic equipment training to ensure one's own safety during research-related activities within the MRI center. Those researchers involved with human participants will also have completed the human subject-training regimen. Those working with experimental animals will follow UCSB's IACUC rules for research with experimental animals. Approved MRI-Researchers can enter all areas of the MRI Suite unescorted, but cannot escort Volunteers or Visitors into the magnet room without the explicit approval of an MRI-operator.

MRI-Operator: These individuals have passed MRI safety and equipment training to ensure safety of self and others during activities in the MRI center. They are also approved for participant screening (metal, pregnancy, and sound sensitivity). They receive in depth equipment training and knowledge of emergency procedures and are approved for independent operation of the 3T MRI system and access to all areas of the MRI suite. Individuals with an MRI-Operator status must be certified in Basic Cardiac Life Support (BCLS). Those researchers involved with human participants will also have completed the human subject-training regimen. Those working with experimental animals will follow UCSB's IACUC rules for research with experimental animals. The BIC MRI technologist oversees certification of MRI-Operator status and has the right to rescind this privilege at any time.

MRI Safety Training. All persons planning to enter the MR suite in the Psychology East Building for the purposes of conducting research or to be involved in clinical-diagnostic imaging must complete Basic MR Safety Training. Basic MR Safety training will be done on-site by BIC staff and consists of a presentation that includes viewing of a Siemens safety tape. This format will give individuals a chance to ask questions and get answers to any concerns that they might have. Initial training also includes a familiarization with the facility. Once initial training is complete, yearly refresher courses may be done

entirely on-line. The BIC administrative assistant will maintain a log of currency in safety training for all MRI-researchers and operators.

Individuals seeking to become MRI-Operators must complete an Advanced Safety Training course. This is a more detailed coverage of safety procedures, subject screening procedures and emergency procedures.

Emergency Procedures Training MRI-operators will receive instruction in procedures related to emergency situations involving medical emergencies (such as cardiac arrest) or those presenting an immediate threat to human life or to the facility infrastructure. This training is recommended, but not required for MRI-researchers. As indicated below in the section of MRI System Operation, at least two people will be required to be present for all MRI sessions in which there is a human subject, one of whom is trained as an MRI-Operator, which includes emergency training. Work involving materials or MRI phantoms can occur with a single MRI-operator without an assistant.

Adverse Event Training Adverse events are characterized by any undesirable experience associated with the MRI scanning session. MRI-operators will receive instruction on procedures related to adverse events, including but not limited to headache, nausea, warming or burning sensation, back pain, any expression of moderate to major discomfort, or any request to discontinue the scan for any reason. In the event of an adverse experience the MRI scanning session will be terminated immediately and an incident report will be filed with the BIC administrator. For longitudinal studies, in the case of more than two adverse events under the same scanning protocol, the BIC suggests complete termination of the study for the participant.

MRI system operations. At the discretion of the BIC, certain **MRI-Researchers** may be trained and certified to operate the MRI system as an **MRI-Operator**. Only UCSB-employed faculty, post-doctoral fellows and graduate students may be certified to operate the MRI system for research. For clinical use, a board certified MRI technologist with specific training on the 3T system may also operate the system as an **MRI-Operator**. The UCSB MRI technologist will conduct MRI system operation and related training. Certification to operate the MRI system will be conferred by the BIC Director upon the determination of competency and recommendation of the MRI Technologist. Approval will be based upon completion of an oral examination and hands on competency exam. The training will involve on-site observation and supervised practice in the operational procedures of the MRI system, and safety and emergency protocols. Anyone certified to operate the MRI system must also have received Emergency Procedures Training.

Renewal of MRI Safety Training. Biennial hands-on refresher training will be required of all certified research personnel. Additional ad hoc training may occur due to newly developed safety guidelines.

TRAINING PROGRAM CONTENTS

Basic Safety Training

- Watch Siemens safety video
- Site specific orientation
- Review of safety posters and signage (see Exhibit D)
- Emergency evacuation plan
- De-metaling
- Hearing protection

Emergency procedures

- Location and use of Emergency Power Shutdown Buttons
- Location and use of Magnet Stop buttons

- Patient table emergency release
- Medical Emergency procedure
- Quench procedure

Scanner Operations Training

- Subject screening procedures
- Hearing protection safeguards
- Squeeze ball
- Subject preparation
- Patient table controls
- Minimum 6 hours of shadowing BIC personnel performing magnet operations
- System start-up and shut-down procedure
- Routine scanning
- New patient registration
- Protocol selection
- Prescription
- Measurement (scanning)
- Data archival and retrieval
- Printing images
- Logging
- Patient monitoring (intercom) system
- Incidental finding protocol
- Oxygen sensor location
- Coil handling and storage
- Linens storage and use
- Knows how to access data on cryogen levels
- Knowledge of SAR and stimulation warnings
- QA procedures
 - Phantom placement and scanning

Orientation for non-Research Personnel

Non-research personnel (such as custodians and other members of the Facilities Management team) who may require routine access to scanner or equipment room must receive an orientation that includes

- Basic familiarity with the hazards associated with the magnetic field
 - Missile effect
 - Malfunction of implanted medical devices
- Familiarity with the layout of the suite
 - Location and meaning a magnetic field
 - Location of scanner
- Instruction to attend to and obey all posted signs

SECTION 4: SITE ACCESS AND RESTRICTION POLICY

This section describes procedures designed to ensure a safe MR environment by maintaining controlled access to areas assigned to the BIC in and around the MRI suite.

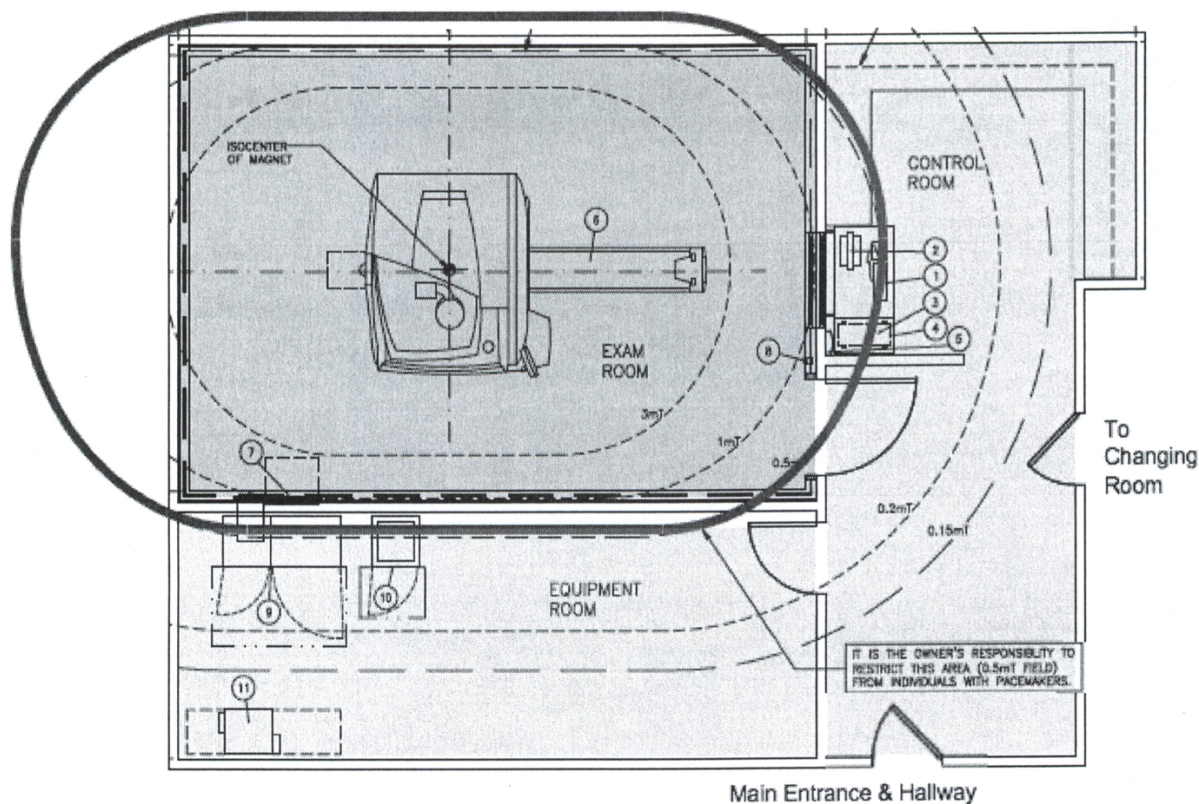
See Section 9 for additional personnel categories and training requirements in response to Coronavirus (COVID-19) pandemic.

At the discretion of the BIC, Section 9 procedures will supersede Personnel Categories and training requirements as detailed in Section 3.

BIC SAFETY ZONES

Lobby, hallways, changing room and bathrooms in the basement of Psychology East building pose no safety hazard. However, because they lead into the MRI area access to these safe areas is restricted as described below.

The MRI suite in the Psychology East Building is a restricted area and is divided into two safety zones as indicated on the following Safety Zone Map. These zones are color coded in blue and red and each zone represents a progressively greater level of access restriction. The thick yellow/black line represents the .5mT line. Persons with pacemakers are never permitted to entering into this area.



Control and Equipment Rooms (Blue zone): Highly restricted area (magnetic field < .5 mT). All visitors, patients and human subject volunteers entering the control or equipment rooms require escort

by an MRI-operator or MRI-researcher. No person with a pacemaker may enter either of these rooms. MRI researchers and MRI operators have unrestricted access to the control and equipment room.

Scanner Room (Red zone): Exclusion area, potentially hazardous zone (magnetic field > .5 mT). **All** persons entering the scanner room, including MRI-researchers, human subject volunteers, patients and visitors **must** fill out and sign an appropriate screening form. All persons entering this area must first remove all metallic and electronic objects. No volunteer, patient or visitor is permitted in the scanner room unless supervised by an MRI-operator. MRI-researchers and MRI-operators have unrestricted access to these rooms.

Appropriate warning signs about magnetic fields are posted at entry points in the doorway between the waiting room and hallway leading to the scanner control room, on the control room door, on the secondary door leading to the changing room and on the magnet room door. Entrance to magnet room is marked with additional signage stating, "The magnet is always on".

MRI KEY ACCESS

Access to the control room via either entrance into the MRI suite is controlled by card key access.

- Access is allowed for the director, associate director, MRI technologist, MRI administrator, certified MR-operators and MRI-researchers.

PROCEDURES FOR PERSONNEL AND ACCESS RESTRICTIONS:

- a. Volunteers, visitors and unaccompanied individuals will enter the MRI waiting room via the North elevator or stairwell. This is an unrestricted area from 8-5 and requires key access after-hours.
- b. A locked door separates the waiting room from a general use hallway that leads to the MRI center. The hallway also leads to the Grafton and Miller laboratories. Only those with key access described above, departmental staff and members of the Grafton and Miller laboratories can enter this hallway.
- c. A separate locked door leads to the MRI control room from the main hallway. Only those with MRI Key Access authority can enter this door.
- d. A second locked door leads to the MRI control room from a changing room area. Only those with MRI Key Access authority can enter or exit this door.
- e. Any subject, patient or visitor entering the magnet room must be accompanied by a certified MRI-operator after metal screening.
- f. Volunteers and patients are generally not permitted in the Equipment Room. Exceptions are vendors of specialized MRI-related equipment and University staff or guests that have special needs to enter the Equipment Room.
- g. Generally, Visitors are not permitted in the magnet room. Exceptions include parents or guardians of minors or of special populations, such and volunteers or patients with diminished cognitive capacity. Other exceptions are vendors of specialized MRI-related equipment and University staff or guests that have special needs to enter the Magnet Room. Visitors that intend to enter the magnet or room must be screened for MRI safety and sign a completed screening form prior to entering either room.

Screening procedure:

All individuals, including volunteer research participants, patients, visitors, technologists, researchers, ancillary support staff, custodial workers, and maintenance and service providers, must be oriented and verbally pre-screened for MRI safety prior to admittance into the magnet room. The pre-screening has two components. Those with pacemakers or electronic implants are not allowed in any of the MRI

areas. Those individuals with metallic implants, tattoos, piercing or other body metal are not allowed in the magnet or equipment room unless first cleared by the BIC director or associate directors. No person may enter the magnet or equipment room without proper screening for metal objects on their person. Section 7 provides additional details about the screening procedures.

Pregnancy

Pregnant women are not permitted in the magnet room during scanner operation, except in cases where IRB approval to include pregnant women in experimental procedures has been sought and approved or for clinical diagnostic purposes.

SECTION 5: MRI SYSTEM OPERATION

This section describes the procedures and policies for operating the 3T MRI system safely and effectively according to an established set of criteria that defines who may operate the MRI system.

Definitions:

MRI SYSTEM: Siemens 3T Prisma Fit

RESEARCH AGREEMENT: : Contractual agreement between Siemens Healthineers (Siemens), Center for Magnetic Resonance Research at The University of Minnesota (CMRR), University of Southern California (USC) Stevens Center for Innovation, and Regents of University of California providing services and materials between the four organizations.

PRODUCT: MRI sequences or hardware provided by the manufacturer (Siemens); these have received full FDA review and approval.

PROTOTYPE: MRI sequences or hardware provided by Siemens that is a first of its kind for test; the software or hardware has followed FDA guidelines but has not received review or approval.

WORKS-IN-PROGRESS (WIPs): MRI sequences and hardware that is provided by the manufacturer according to terms of a research agreement; the software or hardware has followed FDA guidelines but has not received review or approval.

CUSTOM: MRI sequences and hardware written or constructed, respectively, at UCSB or by third-party vendors or collaborators. The software or hardware has followed FDA guidelines but has not received review or approval.

BIC oversight. The BIC has established a structure to provide oversight of MRI system operations. The BIC oversight does not override existing University or IRB policies. The Oversight Committee of the BIC and the BIC director will have joint oversight regarding the safe operation of the 3T MRI system.

Operation by BIC Personnel. Only MRI-operators can use the MRI system. They must have received specific training in operation of the 3T MRI system and have received certification under authority of the Director. A second individual certified as an MRI-researcher or above training must be present to assist the MRI-operator during research with human volunteers or experimental animals. The exception is that board certified; state licensed MRI technologists may operate the scanner alone.

Siemens, The Remy Group, 626 Holdings LLC, engineering personnel may operate the MRI system in accordance with the manufacturer's service agreement.

Training procedures. Training and certification in the operation of the MRI system will follow the procedures outlined in Section 2, Training Requirements, *MRI system Operations and Section 9, Personal Health, Safety Procedures*. Unless otherwise specified, certification will apply to product sequences only (see next section).

Experimental MR software and hardware. Most researchers and all clinical procedures will use 'product' software and hardware. Researchers seeking to use non-product WIPs, prototype, or custom software and hardware may do so only with IRB approval. Use of prototype, WIP, and custom software will require a password, entered on the MRI system control console. This password will be disseminated only to those researchers or BIC personnel that require use of the WIPs or prototypes. Size permitting, prototype, WIP, or custom hardware will be stored in a locked area, available only to those researchers designated for its use. The Oversight Committee will determine who will have access to the password(s) required to implemented non-product MR sequences. .

Compliance. Use of the MRI system will ultimately be controlled and monitored by a log system. This is updated by the Administrative assistant and MRI technologist.

SECTION 6: EMERGENCY RESPONSE

This section will describe procedures and policies relevant to life threatening emergencies at the UCSB 3T MRI suite by identifying responsibilities and authorizing staff to institute emergency measures per established American Heart Association protocols within the scope of his/her demonstrated competence.

Medical Emergency

1. In the event of a medical emergency, the MRI-operator will instruct the second individual, who is required to be present for all human studies, to call UCSB Public Safety from a campus phone and to identify the event and location (Psychology East Basement 0804). Emergency Response personnel should be directed to the North entrance closest to the BIC facility. If the research participant or patient is within the bore of the MRI system, the MRI operator/designee will engage TABLE STOP and manually pull the research participant out of magnet bore.
2. The operator will then transfer the research participant to a non-ferrous stretcher that will be available in the magnet room.
3. The operator will then remove the research participant from the magnet room to the Waiting Room.
4. The operator will then secure the control and magnet room doors to prevent entry by first responders. The MRI-operator is responsible to ensure no one enters the magnet room without proper screening for MRI safety.
5. An on-site individual certified in BCLS will start CPR if necessary.
6. The BIC staff or Laboratory personnel will cede responsibility to emergency responders as they enter the Waiting Room, assisting the 1st responders as requested.
7. The BIC staff will file an incident report and notify appropriate University personnel. The following should be notified:
 - a. UCSB Department of Public Safety.
 - b. UCSB Office of Environmental Health and Safety
 - c. UCSB Office of Insurance & Risk (if involving injury or which may result in an insurance claim.)

MRI system quench

The MRI magnet is maintained at a high field strength by means of super-cooling its conductive loops of wire with liquid helium, which is at an extremely low temperature – close to absolute zero (about 4°K). In certain circumstances, this helium may be rapidly vented off, warming the magnet and causing it to quickly lose its magnetic field. This is known as a “quench.” A quench may be initiated either in a controlled fashion by pressing one of the two Magnet Stop buttons, in which case the helium is safely vented to the outside of the building or, in extraordinary situations, such as an earthquake or an explosion, it is possible for an uncontrolled quench to occur, in which case the helium may vent into the room making breathing difficult.

Controlled quench

A controlled quench should only be initiated by authorized personnel in the event of a potentially life-threatening emergency, such as an individual in respiratory distress being pinned to the magnet by a metallic object. A quench of the magnet is extremely expensive and has the potential to damage the equipment. In non-life threatening situations, such as a piece of equipment being pinned against the magnet, no one should initiate a quench. If it is determined that a potentially life-threatening situation exists, the operator or his/her designee should:

1. Evacuate the magnet room, if possible

2. Depress one of the two Magnet Stop buttons. One is located on the wall of the magnet room and the other is to the left of the operator console. Both are located under plates of Plexiglas, which must be lifted, to prevent them from being pressed accidentally.
3. The magnetic field will dissipate in approximately one minute.
4. If the quench was initiated because of a medical emergency, the procedures listed above under Medical Emergency should be followed.
5. After ensuring that the magnet and equipment rooms are secure and that all individuals have exited these areas, inform Siemens of the quench.
6. File incident report and notify appropriate University personnel. The following should be notified:
 - UCSB Department of Public Safety.
 - UCSB Office of Environmental Health and Safety
 - UCSB Office of Insurance & Risk (if involving injury or which may result in an insurance claim).

Uncontrolled quench

1. In the event of a spontaneous 'quench' of the MRI system; that is, a total venting of the liquid helium, and the research participant or experimenters are within the room containing the MRI system, the MRI-operator will immediately implement the evacuation of everyone from the magnet and equipment rooms and close the access doors.
2. Remove research participant and others from magnet room.
3. Secure magnet room door. The MRI magnet operator is responsible to ensure no one enters magnet room without proper screening for MRI safety. Note that even in the event of a quench, a significant magnetic field may remain for some period of time.
4. After ensuring the magnet and equipment rooms are secure and that all individuals have exited these areas, inform Siemens of the quench.

Electrical Fire

1. In the event of smoke or flames are detected in the vicinity of the electrical equipment, the operator should press the red Emergency Power Shutdown button (**NOT** the red quench button) located in the control room or in the magnet room.
2. Follow standard evacuation procedure (see below).

Evacuation Procedure

1. The MRI-operator is required to securely lock the door to the control room to ensure that no emergency personnel or unscreened emergency equipment are accidentally exposed to the standing magnetic field of the MRI system.
2. In the event of fire in the area of the BIC suite or if it is known that a fire alarm was activated in or near the BIC suite, a member of the BIC staff should proceed to the ground floor level of the North stairwell of the Psychology East Building to meet UCSB Public Safety and Fire Department personnel to provide warning and BIC suite information.
3. All personnel should evacuate the building through the nearest exit (through North stairwell), which leads directly up from the MRI waiting room.
4. Do not reenter the building until granted permission by the Fire Department.

MRI system malfunction

In the event that the MRI system malfunctions, the MRI-operator must log a service call to the service arm of Siemens Medical Solutions by calling Siemens "Up-Time" at 800-888-7436. Non-exhaustive reasons for logging a service call include the following, failure to boot or reboot the MRI system; system default messages; magnet stop alarms; and chiller malfunctions. The TIM Trio scanner has the following number, which is required when logging a service call: 198097.

SECTION 7: MRI EQUIPMENT SAFETY INSPECTION AND STORAGE POLICY

This section provides policies and procedures for handling equipment in the MRI area. The section aims to establish a protocol for the detection of metallic (ferrous) objects prior to entering the area of the MR system to prevent injuries or damage related to the “missile effect”.

Definitions:

FERROUS is defined as a property of some substances including iron and some alloys, in which the application of a weak magnetic field induces high magnetism. Iron, cobalt and nickel are ferromagnetic metals.

MISSILE EFFECT is the result of the fringe field attracting ferromagnetic objects into the MR system with considerable force. Generally, the force increases as the distance between the object and the magnet bore entrance decreases.

PROCEDURES:

1. All ancillary equipment and supplies to be housed in the Equipment room that could potentially be brought into the Magnet room must be clearly labeled ***MRI Safe*** or ***MRI Not Safe***. Tags with large print will become affixed to all such devices brought into the Magnet room.
2. Any temporary equipment or supplies must be inspected for ferrous properties by an MRI-operator. A hand-held magnet and an electronic metal detector will be located in the Control room for this purpose.
3. Only ***MRI Safe*** equipment and devices are permitted in the MRI room.

4. WARNINGS:

- Magnetized objects introduced into the magnetic field become projectiles. Device malfunctions can occur.
- Devices used in the MRI system room must be compatible with the field strength of the MR system.
- Devices compatible with 1.5T systems may be unsuitable for 3T.
- Injury to research participants and personnel can occur if resuscitation systems, defibrillators, or metallic crash carts are brought into the MRI system room.

SECTION 8: RESEARCH PARTICIPANT SCREENING AND SAFETY GUIDELINES

The following establish guidelines designed to prevent accidents due to interactions with the MR magnetic field and the MR system. The policy covers research participants, patients experimental animals and research staff regarding procedures related to MR imaging. These guidelines will ensure a participant's safety by implementing a complete and effective MR safety screening process. Additionally, this document provides MR staff, researchers, and support staff with specific guidelines regarding exclusions for MR procedures.

Definitions

MRI: Magnetic Resonance Imaging

SCREENING: Interview process in which a volunteer is asked for pertinent health and lifestyle information that could indicate a contraindication to exposure to the static and gradient magnetic fields.

EXCLUSION CRITERIA: Designated standards established by ACR guidelines as unsafe for an MRI exam.

Screening Forms

The following approved screening form will be used to screen an individual for MR safety.

Screening Form for Patients and Volunteer Subjects (Exhibit C). This form **must** be used for any individual who will be undergoing an MRI scan. The form must be signed and dated by both the volunteer and by the individual doing the screening. This form will also be used for a parent or guardian that will remain in the magnet room during the conduct of a MRI session.

Prescreening

Researchers are encouraged to prescreen their volunteers for MRI contraindications prior to scheduling them for scanning. Prescreening lessens the chance that scan sessions will have to be cancelled at the last minute because of volunteer MRI incompatibility thereby causing inconvenience to staff, researchers and to the volunteer. Prescreening may be done verbally or in writing and the researcher is not required to submit a copy of any prescreening paperwork to the BIC. NOTE: All individuals **must** be formally screened on-site according to the procedures outlined in this section prior to entering the magnet room.

Human Research Participant Screening

At the time of check-in subjects or patients are asked to complete a screening form to determine the presence of ferromagnetic and other metallic objects (Exhibit C). The on-site screening can be administered by an MRI-Researcher or MRI-Operator. If a research participant does not have the mental capacity to answer the screening questions on the form or is underage, then a family member, a guardian, or a healthcare professional will assist in completing the screening form accurately. Interpreters must be provided if needed to complete the screening process for those without adequate English language competence. The MRI-operator will additionally verbally screen the volunteer prior to entering the magnet room. The MRI-operator is ultimately responsible for ensuring that all persons entering the magnet room have been properly screened.

Pregnancy. Females that self-report pregnancy will be excluded from participation unless the protocol specifically has pregnancy as an inclusion criterion.

Visitor Screening

With minor exceptions, no visitors may enter the magnet room. Exceptions include parents of children receiving an MRI and guardians or obligatory health-care providers of research participants or special University officials or guests. As noted above, these individuals will undergo MR safety screening equivalent to that for research volunteers or patients. In some other cases, equipment vendors or

visiting researchers may enter the magnet room when accompanied by BIC personnel. These special visitors must also undergo MRI safety screening and complete and sign a screening form. The MRI Screening form for Non-Volunteers may be used for this purpose.

Medical devices and objects

If the research participant, patient or visitor indicates having the presence of an implanted medical device on the MR screening form, it is obligatory to obtain the exact name of the device and the manufacturer prior to entry into the magnet room. This information is necessary for the MRI system operator or researcher to verify MR compatibility of the implant or device in the Reference Manual for Magnetic Resonance Safety by Frank G. Shellock, Ph.D.¹ or by accessing the MR safety web site (www.mrisafety.com), or by contacting the manufacturer of the implant directly to confirm safety testing at 3T. This documentation will be attached to subjects screening information to be filed with consent forms. For all MR studies, information identifying an implanted object or device must be documented in writing on the MRI Screening Form.

Dental bridges, braces and other fixed materials are not absolute contraindications for imaging. However, these scans should be evaluated for excessive artifacts.

Tattoos

Tattoos are not an absolute contraindication for MRI procedures. Heavily tattooed individuals, particularly of the head and neck should be instructed to be alert for any heating sensations and to notify the magnet operator (by using the squeeze ball) should they experience any discomfort. Participants with tattoos may or may not have an MRI based on the opinion of the magnet operator or the researcher.

Orbital (Eye) considerations

Orbital injury. If a research participant reports on the screening form a history of metallic injury to the eye, the participant will be excluded from participating in the MRI study.

Orbital metal exposure. If a research participant indicates a history of metal work on the screening form, the researcher/BIC staff will alert the technologist/responsible person. The technologist will interview the research participant to determine if s/he ever had a foreign body injury to the eye from such metal work, and if the research participant always wore safety glasses or goggles while doing this work. The technologist will document the research participant's answer on the screening form.

Post-operative conditions

If a volunteer has a heart valve, coronary artery bypass clips, IVC filter, limb or joint replacement or pinning, spine fusion or Harrington rod or intra-abdominal clips, applicable MR compatibility and the date of the surgery must be known.

Pacer wires in the chest are a contraindication for an MR exam.

Hearing Protection

Functional MRI scanning produces a loud (94-104 dB) high frequency tone that can cause hearing damage if appropriate hearing protection is not used. This level of noise corresponds to sounds emitted by a car engine or jack hammer. For sound abatement three sizes of earplugs are available: the Honeywell Howard Leight MAX Roll Down Foam Ear Plug (NRR:33dB), 3M Classic Foam Earplugs (NRR:29dB), and Honeywell Howard Leight FIRM FIT (NRR:30dB). To ensure successful placement by the participant a number of safety measures are in place: 1) one-on-one training, including a demonstration of how to pull the earlobe down and slightly to the side to fully open the ear canal; 2) posters are provided in the MRI magnet room and changing rooms to illustrate proper insertion technique, including the 'Roll, Pull and Hold' method for soft roll earplugs; 3) two safety videos are readily available to the participant for added clarity as needed (Exhibit D). A ~1 kilohertz sound test will be performed before and after earplug placement. Feedback and correction will be offered by the MR

operator and/or researcher if the earplug(s) are loose, sticking out of the ear, or after the sound check is performed. If a good fit is not obtainable, a different size earplug will be offered. Fitting procedures will then be repeated. If a proper fit is not obtainable or uncomfortable the MRI session will be cancelled.

Earplug Placement Videos

These video are required for MRI Operators and MRI Researchers interacting with the participant as part of standard safety training:

Honeywell Howard Leight Earplugs Instruction Video:

<https://drive.google.com/file/d/1G66qZMGT7OfecBJeJQqFy0gjV7U5lYz/view?usp=sharing>

3M Classic Foam Earplugs Instruction Video:

https://drive.google.com/file/d/1J_1eU6hzmFND26bejL2jUqDwKGmGr4rz/view?usp=sharing

Final preparations

Before entering the Magnet room, research participants must remove metallic objects from their person including: jewelry, bobby pins, barrettes, wigs or hairpieces, coins, pens, pencils, paper clips, lighters, keys, wallets, credit cards, belts, zippers and all other potential hazardous objects or apparel.

Following recommendations set by the ACR, all research volunteers and patients may be required to remove street clothing and change into clothing provided by BIC facility. To prevent sub-optimum imaging due to artifacts, the magnet operator or assistant will prepare research participants for all MRI procedures by requiring removal of any articles of clothing adorned with zippers, snaps, hooks, appliqués or fabric containing nylon or satin. Heavy applications of make-up must be removed upon the judgment of the magnet operator or researcher. Additionally, the magnet operator or assistant will ensure research participants that will undergo head MRI to remove dentures, partial plates and retainers before the MRI exam.

Experimental Animal Screening

Experimental animals will undergo screening similar to humans, except that the research group will provide answers to the relevant queries about MRI safety. If needed the staff of the Animal Care Facility will interact with the BIC to insure MRI safety of experimental animals.

Incidental Findings with human or experimental animal participants

1. *Identification of potentially abnormal finding while the research participant is still undergoing an MRI procedure.* The operators may elect to stop the procedure if s/he notes a potential structural or functional abnormality. At the end of the procedure, the operator will contact the BIC Director and provide relevant images so as to allow formation of an opinion as to whether the research volunteer should seek a medical opinion about the perceived abnormality. Current IRB policy holds that no research-related images can be provided for diagnostic purposes.
2. *Identification of potentially abnormal result after the research participant has left the facility.* At the end of the procedure, the operator will contact the BIC Director and provide relevant images so as to allow formation of an opinion as to whether the research volunteer should seek a medical opinion about the perceived abnormality. Current IRB policy holds that no research-related images can be provided for diagnostic purposes.

Incident Report

1. An incident report must be submitted when an event occurs that has potential consequences for the infrastructure of the facility or for any adverse event involving a human research volunteer or an experimental animal.
2. A non-exhaustive list of incidents includes: hearing loss possibly related to the MRI sequence generation; heating of skin; ferromagnetic objects striking a research participant; equipment failure that has potential to injure a research participant; death of an experimental animal due to the procedures, etc.
3. The magnet operator must file a report of the incident, co-signed by the relevant PI and laboratory member in charge of the experiments. This report should be submitted to the BIC Administrative Assistant who will notify the BIC Director.

1. Sherlock, Frank G., Ph.D. Reference Manuel for Magnetic Resonance Safety: 2020 Edition.

SECTION 9: PERSONAL HEALTH AND SAFETY PROCEDURES DURING THE COVID-19 PANDEMIC

This section details new policies and operational requirements to mitigate and reduce the risk of exposure to COVID-19 for all visitors, researchers and staff.

1) Personal Health

BIC personnel should stay home if they do not feel well or are experiencing symptoms associated with COVID-19, such as coughing, shortness of breath, difficulty breathing, diarrhea, loss of taste/ smell, or other flu-like symptoms.

Participants:

In order to qualify for the study, participants must pass a COVID-19 symptom tracker (by answering no to all questions) on the day of experiment, prior to arrival. Participants are required to wait outside in courtyard rather than the waiting room. All paperwork should be completed prior to arrival (online via DocuSign). There will be 30 minutes of scheduled cleaning time between each participant.

2) Signage and Posters

Signage reminding all BIC personnel and visitors how to follow health and safety procedures are posted at the main entrance and throughout the MRI suite including dressing rooms and restrooms. Signage included but are not limited to:

- Proper handwashing.
- Covering coughs and sneezes.
- Avoid touching their faces.
- Social distancing.

3) Personal Health and Safety Procedures

A) Hand Sanitation: Gel In, Gel Out:

Proper and frequent handwashing with soap and water for 20 seconds or use of a disinfection gel with 60% alcohol is required and readily available in the MRI suite. A “gel-in”, “gel-out” approach will be used during entry and exit of the following areas:

- Main Entrance
- Control and Equipment Rooms
- Scanner Room
- Dressing Rooms
- Restrooms

B) Face Covering:

Face covering over the nose and mouth is required for all those entering the BIC and are to be worn throughout all research activities. Per CDC guidance, a face covering can be any item of cloth that fits snugly against the side of the face, can be secured with ties or ear loops, has *multiple layers of fabric* and allows for unrestricted breathing. Standard disposable masks will be provided for participants.

The only exception is for volunteers ready to go inside the MRI scanner.

- A pill tray will be provided to the volunteer for face covering storage.
- The MR-Operator will collect the pill tray and store at the end of MR-Table.
- Volunteer will perform hand sanitation and return face covering before exiting the MRI scanner room.

C) Gloves:

Nonsterile gloves made of either latex, nitrile, or vinyl are required when anticipating any physical contact with others and when cleaning and disinfecting workstation surfaces and equipment.

D) Face Shield:

A face shield to protect the face, mouth, nose, and eyes from airborne droplets is required by the MR-Operator inside the MRI scanner room at all times.

E) Social Distancing

Floor marking strips placed throughout the MRI suite will help maintain a social distance of 6 feet between the MR-Operator, Researcher and Volunteer at all times. This is to limit face-to-face contact and decrease the spread of illness.

4) Additional Safety Training Requirements

In addition to the training requirements in Section 3, BIC personnel will complete a COVID-19 related training. This will be done via zoom with the BIC administrator.

COVID-19 Safety Training Update

1) Online portion:

Researchers must complete COVID-19 return to work training through the UCSB learning center. Please provide the BIC administrator with proof of completion (forward certificate of completion email).

2) In person portion:

Researchers must demonstrate proper handwashing/ use and disposal of PPE. They must demonstrate knowledge of protocol adjustments - proper scheduling/ running of participants and proper disinfecting of workspace.

Cleaning and Disinfecting Protocol and Procedures

This section describes surface decontamination to reduce the risk of spreading COVID-19. Cleaning and disinfecting all high-contact surfaces will be required daily. Disinfection will occur upon opening the center every morning, between each participant, and at the end of the workday.

MRI-Operator:

Responsible for cleaning and disinfecting the following areas:

Control Room:

- Siemens system console table and MR-Operator chair
- Siemens system console keyboard and mouse
- Siemens MRI communication system intercom.
- Telephone
- fMRI synchronization 'trigger' box. (Current Designs 932 Box)
- TV Remote Control
- Plexiglass

MRI Room:

- MRI room door handles
- MRI patient table
- MRI and fMRI system components including imaging coils, phantom, projectors, response pads.
- MRI headsets and tubing
- MRI emergency squeeze ball and tubing.

Dressing Room:

- Door handles and Chairs

MRI-Researcher:

Responsible for cleaning and disinfecting the following areas:

- Researcher workstation counter.
- Researcher Chair
- Lumina Response Trigger box and cabling
- Keyspan USB adapter and cabling
- Display Switch
- Eyetracker computer, keyboard and mouse

MRI-Administrator:

Responsible for cleaning and disinfecting the following areas:

- Administrator workstation
- Administrator Chair
- Front door to BIC
- Door to MRI room
- Plexiglass surrounding workstation

Appendix

Exhibit A: UCSB BRAIN IMAGING CENTER STUDY APPLICATION FORM

3T MRI Research Application

(submit to Margaret Hayes, Dept. of Psychology: mqhayes@psych.ucsb.edu)

New Experiment

Renewal

Expedited Review

Experiment Title: _____

Principal Investigator (Faculty member at UCSB): _____

Campus Address: _____

Phone Number: _____

Name/Address/Phone of other Researchers or Investigators: (Coordinator, Grad Stud, Post doc, RA, Non-UCSB PI): _____

Human Subjects Approval Number: _____ Expiration Date: _____

Please attach copies of the following documents:

- 1) *Human Subject Protocol*
- 2) *Consent form*
- 3) *Description of experimental design (see next page)*

Resources requested:

Number of sessions per subject: _____

Number of subjects: _____

Estimated duration of each imaging session: _____

Scans per session (Check all that apply):

- Localizer
- Coplanar anatomic scan
- T1 MPRAGE (standard T1 weighted 3D high resolution anatomic scan)
- T1 FLASH (standard T1 weighted 3D high res anatomic scan, like a GE SPGR)
- T2 SPACE (standard T2 weighted 3D high resolution anatomic scan)
- Gradient Field Map
- fMRI BOLD (standard 2D Single shot with iPAT GRAPPA) Number of runs: _____
- MPRAGE (standard T1 weighted 3D high resolution anatomic scan)
- DTI (number of tensors: _____ (minimum 30 recommended))
- DSI with multiple b0 (0-5,000) (number of tensors: _____ (minimum 30 recommended))
- Arterial Spin Labeling (ASL)
- Other _____

Total Scanning Hours Requested:

Time of day (8am-4pm or after-hours): _____

Who will do the imaging? _____

Funding: (Select one of the following five):

This study is funded by an extramural grant administered by UCSB

Funding Agency: _____

Account to bill: _____

I authorize UCSB Brain Imaging Center to bill directly the above account using electronic accounting: _____

This study funded by another institution

Name and Address of contact to bill studies: _____

This study is for undergraduate instruction: Name of course: _____

This study is supported by startup commitments by the Dean of my school

I am requesting UCSB BIC to subsidize this research as a pilot project

If subsidized by the BIC, describe plans for obtaining future extramural funding:

Stimulus Presentation and Response Detection (Pick all that apply):

LCD back-projection

LCD front-projection

Audio stimuli with Siemens headphones

Audio stimuli with other headphones

Cedrus button box (up to 4 keys)

Current Designs 932 Button Box (up to 6 keys)

Large button box (up to 10 keys)

Joystick

Eyetracker

MRI Compatible EEG

Special requests: _____

Data path:

(How do you want your data?)

Burn a DVD (PC compatible only)

Burn a CD

External hard drive

sftp from MRI center tape archive to local computer

Supplemental Description of Experiment Design:

In addition to providing the protocol submitted to CPHS for your human subject approval, please describe, in one page, your proposed experimental paradigm. Include details of the specific design (block, single event, multi-event, continuous), number of trials per event type, randomization procedure, assessment of orthogonality, triggering method and analysis methods.

For BIC use only: Scan Cost: [] Number of Scan Hours approved: []

Committee Review Date: _____ Renewal Date: _____

Approved for Human subjects? _____

Other Comments: _____

Exhibit B: California Experimental Bill of Rights

Experimental Research Subject's Bill of Rights

California law, under Health & Safety Code §24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Exhibit C: UCSB BRAIN IMAGING CENTER MAGNET SCREENING FORM

UCSB BRAIN IMAGING CENTER MAGNET SCREENING FORM

Date ___ / ___ / _____

Subject ID (place sticker here):

Name _____

Date of Birth ___ / ___ / _____

Age _____ Height _____ Weight _____

Sex (Assigned at Birth) Male Female

Gender _____

- Hispanic or Latino
 - Not Hispanic or Latino

Address _____

City _____ State _____

Zip Code _____

Email Address _____

Phone Number (_____) _____ - _____

- White
 - American Indian / Alaskan Native
 - Asian
 - Native Hawaiian or Other Pacific Islander
 - Black or Native American
 - More Than One Race

- | | NO | YES |
|--|--------------------------|--------------------------|
| 1. Have you ever had a surgery or operation (e.g., arthroscopy, endoscopy, etc.) of any kind? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Have you had a prior diagnostic imaging study or examination with MRI? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Have you experienced any problem related to a previous MRI examination?
If yes, please describe _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.) | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Have you ever done any welding, grinding, or cutting of metal in your lifetime? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Did you wear safety protection for your eyes? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? If yes, please describe _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Are you wearing any silver or copper material lined clothing? (e.g., Lululemon, Under Armor) | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Do you have any other type of implant in your body not covered by the above list?
If yes, type of implant _____ | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Do you have a history of migraines? | <input type="checkbox"/> | <input type="checkbox"/> |

For Female Volunteers:

Are you currently pregnant or is there any possibility that you may be pregnant?
(e.g., late menstrual period)

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

If you have any question regarding an implant, device, or possible metal object, please discuss this with the MRI Technologist or Researcher BEFORE entering the MRI room.

Please indicate if you have any of the following:

- No Yes Dentures or partial plates
- No Yes Head or Neck Tattoo or Permanent Makeup
- No Yes Body piercing jewelry
- No Yes IUD or diaphragm
- No Yes Electronic implant or device

If yes, which of the following apply:

- | | |
|--|--|
| Magnetically-activated implant or device | Cardiac pacemaker |
| Implanted cardioverter defibrillator (ICD) | Aneurysm clip(s) |
| Neurostimulation system | Spinal cord stimulator |
| Internal electrodes or wires | Bone growth/bone fusion stimulator |
| Cochlear, otologic, or other ear implant | Insulin or infusion pump |
| Implanted drug infusion device | Any type of prosthesis (eye, penile, etc.) |
| Heart valve prosthesis | Eyelid spring or wire |
| Artificial or prosthetic limb | Metallic stent, filter, or coil |
| Shunt (spinal or intraventricular) sutures | Joint replacement (hip, knee, etc.) |
| Bone/joint pin, screw, nail, wire, plate, etc. | Radiation seeds or implants |
| Vascular access port and/or catheter | Wire mesh implant |
| | Surgical staples, clips, or metallic |

- No Yes Medication patch (Nicotine, Nitroglycerine, Contraceptive, any transdermal patch)
- No Yes Any metallic fragment or foreign body
- No Yes Any transdermal patch
- No Yes Hearing issues (loss, sensitivity to loud noises, previous excessive noise exposure, or use of hearing aid) If yes, please describe (record frequency/duration): _____
- No Yes Tinnitus (e.g., ringing, clicking, buzzing in one or both ears that may be constant or may come and go) If yes, please describe (record frequency/duration): _____

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form and have had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

NOTE: You may be advised or required to wear earplugs or other hearing protection during the MR procedure to prevent possible problems or hazards related to acoustic noise.

Signature of Person Completing Form _____ Date ____/____/____
Signature

Signature Form Completed by _____
Print Name Relationship to person entering MRI

Form Information Reviewed by _____

Exhibit D: Posters and Signage



Earplug Fitting Instructions

Keys to Successful Hearing Protection with Earplugs

WEAR	MAINTENANCE
<ul style="list-style-type: none"> Read and follow all earplug fitting instructions Avoid overprotection in minimal noise environments - in selecting the best earplug for your situation, consider noise levels and your need to communicate with co-workers or hear warning signals on the job 	<ul style="list-style-type: none"> Inspect earplugs prior to wear for dirt, damage or hardness - discard immediately if compromised For proper hygiene, discard Single-Use earplugs after use With proper maintenance, Multiple-Use earplugs can last for 2-4 weeks; clean with mild soap/water and store in a case when not in use Clean and replace pods on Banded earplugs regularly

No-Roll Foam	Roll-Down Foam	Multiple-Use	Banded
<p>Matrix™</p>	<p>Max®</p>	<p>SmartFit®</p>	<p>QB2HYG®</p>
<p>1</p> <p>Reach over your head with a free hand, pull your ear up and back, and insert the earplug well inside your ear canal.</p>	<p>1</p> <p>With clean hands, roll the entire earplug into narrowest possible crease-free cylinder.</p>	<p>1</p> <p>While holding the stem, reach a hand over your head and gently pull top of your ear up and back.</p>	<p>1</p> <p>Position band under your chin as shown above. Use your hands to press the ear pods well into the ear canal using an inward motion.</p>
<p>2</p> <p>Earplugs should be inserted as shown in this drawing. Stop pushing earplug when your finger touches your ear.</p>	<p>2</p> <p>Reach over your head with a free hand, pull your ear up and back, and insert the earplug well inside your ear canal.</p>	<p>2</p> <p>Insert the earplug so all flanges are well inside your ear canal.</p>	<p>2</p> <p>Protection levels are improved by pulling your ear up and back when fitting as shown.</p>
<p>3</p> <p>If properly fitted, the end of the earplugs should not be visible to someone looking at you from the front.</p>	<p>3</p> <p>Hold for 30 - 40 seconds, until the earplug fully expands in your ear canal. If properly fitted, the end of the earplugs should not be visible to someone looking at you from the front.</p>	<p>3</p> <p>If properly fitted, the tip of the earplug stem may be visible to someone looking at you from the front.</p>	<p>3</p> <p>In a noisy environment, lightly press the band inward with your fingertips as shown. You should not notice a significant difference in noise level.</p>

<p>Do's and Don'ts of Howard Leight® Earplugs</p>	<p>Proper Fit If either or both earplugs do not seem to be fitted properly, remove the earplug and re-insert.</p>	<p>Removal Gently twist earplug while slowly pulling in an outward motion for removal.</p>	<p>Acoustical Check In a noisy environment, with earplugs inserted, cup your hands over your ears and release. Earplugs should block enough noise so that covering your ears with your hands should not result in a significant noise difference.</p>
--	--	---	--

Sperian Protection Australia Pty Ltd
3 Walker St, Braeside, Victoria 3195 Australia
Tel: 3200 123456 Fax: 3200 312456
New Zealand Tel: 0800 322 200
www.sperianprotection.com.au
www.hearingportal.com



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AVAILABLE EAR PLUGS. COLOR, SIZE AND NOISE REDUCTION RATING (NRR)



RED

**LARGE (NRR) 33 dB
USE FIRST**



YELLOW

MEDIUM (NRR) 29 dB



ORANGE

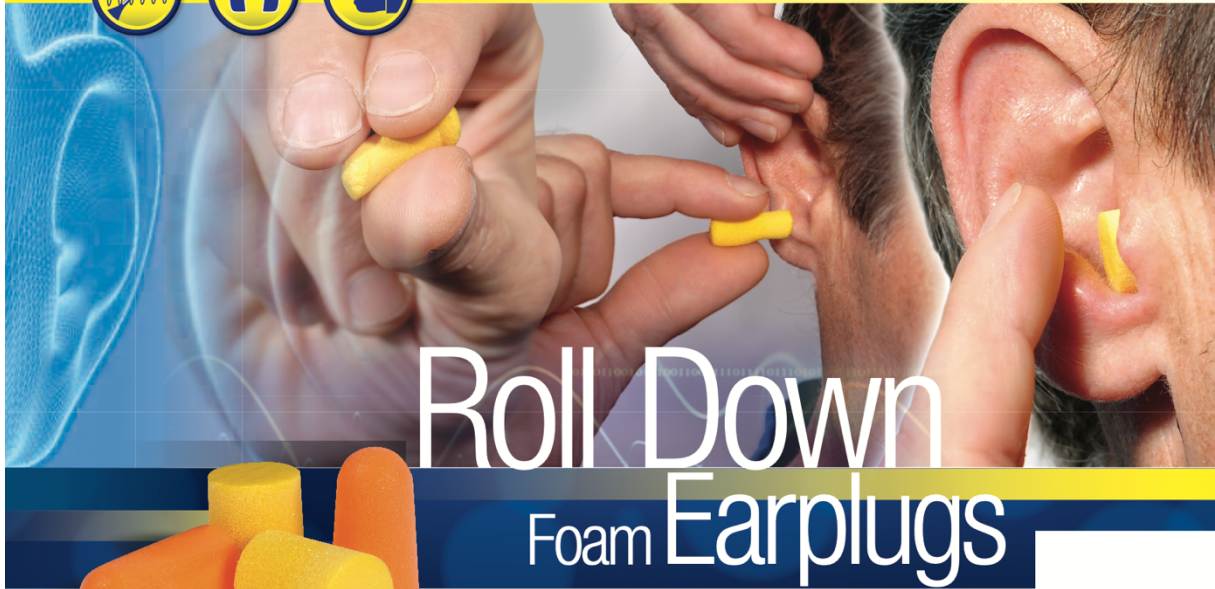
SMALL (NRR) 30 dB

MRI acoustic noise can produce up to 104 dB and may result in temporary or permanent noise induced hearing loss. **Please ensure a proper fit and ask researcher and/or BIC staff for assistance.**

detection

protection

validation



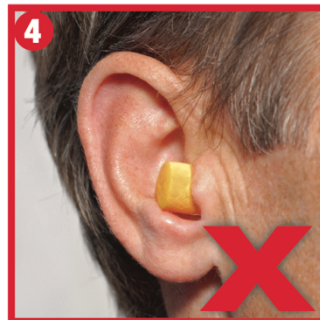
Fitting Instructions

REGULAR size foam earplugs fit most ears well. LARGE size earplugs are also available for larger ear canals, and SMALL size earplugs are available for smaller ear canals. Hands and earplugs should be clean before fitting.

- 1) ROLL earplug slowly with thumb & fingers. Gradually increase pressure to COMPRESS earplug to very thin crease-free cylinder.
- 2) INSERT compressed earplug well into ear canal WHILE PULLING ear outward & upward with opposite hand.
- 3) CHECK FIT after earplug expands in ear: TOUCH earplug. You should feel only the end of earplug.
- 4) If you feel most of earplug outside the ear canal, remove earplug and repeat fitting.

LISTEN to steady loud noise with earplugs in both ears. Cover ears with tightly cupped hands. Noise should sound about the same whether or not ears are covered.

If you cannot obtain a good fit, try a different size or type of hearing protector.



For more information visit www.3M.com/hearing.

The power to protect your world.SM

EAR PELTOR™

3M

© 2013 3M Company. 3M, the E-A-R logo and the color yellow for earplugs are trademarks of, and The Power To Protect Your World is a service mark of 3M Company, used under license in Canada. Peltor is a trademark of 3M Svenska AB, used under license in Canada. 70-0716-2609-0

DANGER!

RESTRICTED ACCESS



STRONG MAGNETIC FIELD

The Magnet is Always On!



- **NO CARDIAC PACEMAKERS OR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDs)**

Persons with certain metallic, electronic, magnetic, or mechanical implants, devices, or objects may not enter this area.

Serious injury may result.

Do not enter this area if you have any question regarding an implant, device, or object. Consult the MRI Technologist or Radiologist.



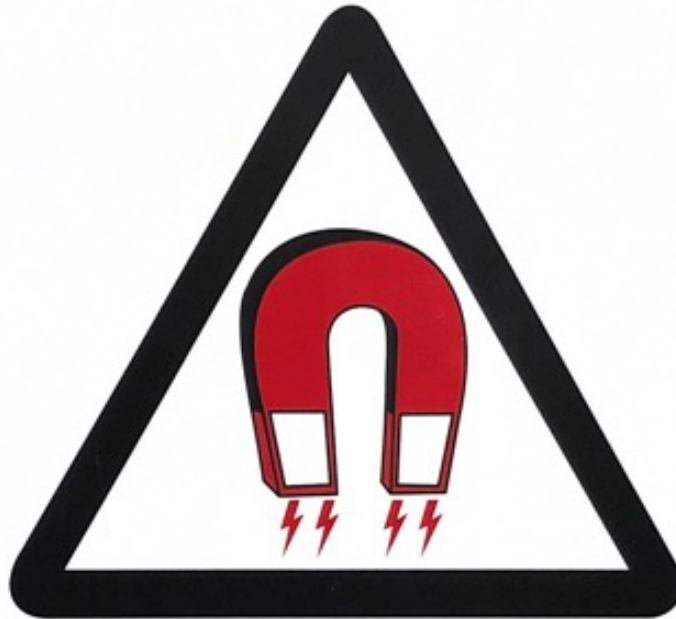
- **NO LOOSE METAL OBJECTS**

Objects made from ferrous materials must not be taken into this area. **Serious injury or property damage may result.**

Electronic objects such as hearing aids, cell phones, and beepers may also be damaged.

¡PELIGRO!

ACCESO PROHIBIDO



CAMPO MAGNÉTICO FUERTE

¡El imán siempre está encendido!



- **NO ENTRE NADIE QUE TIENE MARCAPASOS CARDÍACO O DESFIBRILADOR CARDIOVERTER IMPLANTABLE (ICD).**

La entrada en esta área por personas con ciertos implantes, aparatos, objetos metálicos puede resultar en **heridas serias**.

No entre en esta área si tiene cualquier pregunta sobre un implante, aparato, o objeto. Consulte con el tecnólogo de MRI o el radiólogo.



- **NO OBJETOS SUELTOS HECHOS DE METAL**

Objetos hechos de materiales ferrosos (de hierro) no se pueden llevar en esta área. **Herida seria corporal o daño al objeto puede resultar.** También se puede dañar objetos electrónicos como aparatos del oído, teléfonos celulares, y localizadores.