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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 supercede established University polices 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: grafton@psych.ucsb.edu

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

UCSB Brain Imaging Center
Department of Psychology
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 USB’s Human Research Protections Office. [http://research.ucsb.edu/compliance/index2.shtml](http://research.ucsb.edu/compliance/index2.shtml)

Principal Investigators should refer to Exhibit B for more details about MRI related IRB procedures and policies.

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 has 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 having a protocol that involves human subjects are required to have completed the training for research with human subjects (see Section 2, Training Requirements, for details). [http://hstraining.orda.ucsb.edu/IntroPage.htm](http://hstraining.orda.ucsb.edu/IntroPage.htm)

c. **Experimental Animal Training.** All researchers having a protocol that involves experimental animals are required to complete all necessary training for the proper use of experimental animals. [http://research.ucsb.edu/iacuc/training_animal_users.shtml](http://research.ucsb.edu/iacuc/training_animal_users.shtml)

d. **Emergency Procedures Training.** For all protocols involving human subjects, at least one researcher must be present during each MRI data acquisition session that has 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 (Exhibit C) prior to using USB’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:

   Lee Mudrick
   Risk Management and Insurance
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 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 Psychology
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**

   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 USB’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:
   Lee Mudrick
   Risk Management and Insurance
   3203 saasb
   UCSB
   Santa Barbara, CA 93106-2090
   Business office
   Email: Lee.Mudrick@buss.ucsb.edu
   Phone: 805-893-2860

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.

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 ones 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). 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.

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
- 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
- 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
- Patient table controls
- 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
  o 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
  o Missile effect
  o Malfunction of implanted medical devices
• Familiarity with the layout of the suite
  o Location and meaning a magnetic field
  o 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.

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 red 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 Blascovich laboratories. Only those with key access described above, departmental staff and members of the Grafton and Blascovich 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 TIM Trio

**Research Agreement**: Contractual agreement between Siemens and Regents of University of California providing services and materials between the two 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 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*. 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 Room B06). 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 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 E). 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 E). 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 can enter the magnet room. Exceptions include parents of children receiving an MRI and guardians or obligatory health-care providers of demented 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. 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. Any 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
All volunteers and all visitors or researchers that will remain in the magnet room during scanning are required to wear hearing protection in the form of ear plugs, sound-attenuating headphones, or both.

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 Reports

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.

Appendix 1 Application form

UCSB Brain Imaging Center

3T MRI Research Application
(submit to Phil Beach, Dept. of Psychology: beach@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):

[ ] Coplanar anatomic scan
[ ] (MRI BOLD (standard 2D Single shot with iPAT GRAPPA) Number of runs:____
[ ] MPRAGE (standard T1 weighted 3D high resolution anatomic scan)
[ ] FLASH (standard T1 weighted 3D high res anatomic scan, like a GE SPGR )
[ ] DTI (number of tensors:_______(minimum 30 recommended)
[ ] Gradient Field Map
[ ] 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)
[ ] Large button box (up to 10 keys)
[ ] Joystick
[ ] 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: ____________________________________________________________________
Waiver of Liability, Assumption of Risk & Indemnity Agreement

Facilities Use Waiver - Non-Athletic

Department: __________________________  Name of Facility/Class: __________________________

Waiver: In consideration of permission to use, today and all future dates, the property, facilities, staff, equipment and services of __________________________, I, for myself, my heirs, personal representative or assigns, do hereby release, waive, discharge, and covenant not to sue The Regents of the University of California, its directors, officers, employees, and agents from liability from any and all claims, including the negligence of __________________________ resulting in personal injury, accidents, or illnesses (including death), and property loss arising from, but not limited to, participation in activities, classes, observation, and use of facilities, premises, or equipment.

Assumption of Risks: The use of University property, facilities, staff, equipment, and/or services carries with it certain inherent risks that cannot be eliminated regardless of the care taken to avoid injuries. __________________________ has facilities for and provides activities such as social events, community outreach, clinics, classes, camps and day care. Some of these involve situations, environments, or activities that may lead to illness, physical injuries, and psychological stress or damage.

The specific risks vary from one activity to another, but the risks range from 1) minor injuries such as scratches, bruises, sprains, and embarrassment 2) major injuries such as joint or back injuries, heart attacks, head injuries, and psychological trauma 3) catastrophic injuries including paralysis and death.

I have read the previous paragraphs and I know, understand, and appreciate these and other risks that are inherent in the activities made possible by __________________________. I hereby assert that my participation is voluntary and that I knowingly assume all such risks.

Indemnification and Hold Harmless: I also agree to INDEMNIFY AND HOLD The Regents of the University of California HARMLESS from any and all claims, actions, suits, procedures, costs, expenses, damages and liabilities, including attorney's fees brought as a result of my involvement at __________________________, and to reimburse them for any such expenses incurred.

Severability: The undersigned further expressly agrees that the foregoing waiver and assumption of risks agreement is intended to be as broad and inclusive as is permitted by the law of the State of California and that if any portion thereof is held invalid, it is agreed that the balance shall, notwithstanding, continue in full legal force and effect.

Acknowledgment of Understanding: I have read this waiver of liability, assumption of risk, and indemnity agreement, fully understand its terms, and understand that I am giving up substantial rights, including my right to sue. I acknowledge that I am signing the agreement freely and voluntarily, and intend by my signature to be a complete and unconditional release of all liability to the greatest extent allowed by law.

Signature of Participant: __________________________  Print Name of Participant: __________________________  Date: __________________________  Age (If Minor): __________________________

Signature of Parent/Guardian of Participant if Minor: __________________________  Print Name of Parent/Guardian of Participant if Minor: __________________________  Date: __________________________

Exhibit B
Appendix C: UCSB BRAIN IMAGING CENTER MAGNET SCREENING FORM

Date _____/_____/_____

Subject Number ______________________

Name ______________________________________________
Age ________ Height ________ Weight ________

Last name  First name  Middle Initial

Date of Birth _____/_____/_____  Male ρ Female ρ

month      day         year

Address ___________________________________________

City  ___________________________________________

State  _______________________  Zip Code ___________

Telephone (home) (_____) _____-________

1. Have you ever had surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind?  ρ No ρ Yes
   If yes, please indicate date and type of surgery:

2. Have you had a prior diagnostic imaging study or examination with MRI?  ρ No ρ Yes

3. Have you experienced any problem related to a previous MRI examination or MR procedure?  ρ No ρ Yes
   If yes, please describe: ________________________________________________________

4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)?  ρ No ρ Yes
   If yes, please describe: ________________________________________________________

5. Have you ever done any welding, grinding or cutting of metal in your lifetime?  ρ No ρ Yes

6. Did you wear safety protection for your eyes?  ρ No ρ Yes

7. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)?  ρ No ρ Yes
   If yes, please describe: ________________________________________________________

For Female Volunteers:

8. Are you currently pregnant or is there any possibility that you may be pregnant (e.g., late menstrual period)?  ρ No ρ Yes
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:

- Dentures or partial plates: Yes / No
- Head or Neck Tattoo or Permanent Makeup: Yes / No
- Body piercing jewelry: Yes / No
- IUD or diaphragm: Yes / No
- Electronic implant or device: Yes / No
  
  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)
  - Vascular access port and/or catheter
  - Wire mesh implant
  - Surgical staples, clips, or metallic sutures
  - Joint replacement (hip, knee, etc.)
  - Bone/joint pin, screw, nail, wire, plate, etc.
  - Radiation seeds or implants

- Medication patch (Nicotine, Nitroglycerine): Yes / No
- Any metallic fragment or foreign body: Yes / No
- Hearing aid: Yes / No  
  \( \text{(Remove before entering MR system room)} \)

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.

Signature of Person Completing Form ____________________________ Date ___/___/____

Signature

Form Completed By ____________________________ ____________________________

Print name Relationship to person entering magnet room

Form Information Reviewed By ____________________________ ____________________________

Print name Signature