

**CMU-Pitt
Brain Imaging Data Generation & Education
(BRIDGE)
Center**

Note: Provisional name.

*A collaborative research facility of
Carnegie Mellon University & University of Pittsburgh
Pittsburgh, PA 15213
412.268.7140*

Policies, Procedures, & Safety Manual

Version 1.5 – February 21, 2019

By conducting research at the BRIDGE Center, you acknowledge that you have read, understand, and will abide by the policies and procedures described herein. Principal Investigators are responsible for all lab members conducting research at the center, including that they are fully qualified with respect to safety training, human subjects training, and familiarity with the policies and procedures in this manual. This manual will be continually updated with version indicated in the footer. The policies that apply to a scanning session are those in the current version of this document, according to the scanning session date.



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Acknowledgements: This document was created in part by drawing on text and ideas from numerous other documents of this type from other MRI research centers. Some informational text was taken directly from other centers or resources. References for these other texts will be provided in v1.3 of this document.

SECTION 1: BRIDGE CENTER INTRODUCTION

1.1 Safety & Emergency Contacts

In an Emergency for Fastest Response for Police, Ambulance, & Fire:

Call CMU Police: 8-2323 from a campus phone (412-268-2323)
Center Location: Wean Hall 3604

In the event of an incident related to safety, contact:

Dr. John Pyles, Scientific Operations Director & Safety Committee Chair

jpyles@cmu.edu

Mobile phone: 949-300-8567

Office phone: 412-268-3647

and

Scott Kurdilla, MR Technologist & Safety Officer

kurdilla@cmu.edu

Control Room & Office: 412-268-7140

Other Center Personnel:

Dr. Timothy Verstynen, Co-Director, (timothyv@andrew.cmu.edu)

Dr. Walter Schneider, Co-Director, (wvs@pitt.edu)

Mark Vignone, MR Technologist, (vignone@pitt.edu)

Kathy Majors, Financial Administrator, (km4m@andrew.cmu.edu)

Ginger Placone, General Administrator, (gingerp@andrew.cmu.edu)

Emily Clarke, General Administrator, (ecb27@pitt.edu)

Other CMU Safety Contacts:

Environmental Health and Safety: 412-268-8192

Facilities Management: 412-268-2910

1.2 Introduction to the Center

The CMU-Pitt Brain Imaging Data Generation & Education (BRIDGE) Center is a cutting-edge, collaborative MRI facility that is jointly operated by the University of Pittsburgh and Carnegie Mellon University. The center is a research-only neuroimaging center, meaning that it is designed exclusively to support basic science research.

The philosophy of the BRIDGE Center is premised off four core principles:

- An imaging center is both a research tool and an education tool.
- An imaging center strives to remove barriers to access.
- An imaging center serves as a research community hub.
- An imaging center fosters innovation.

These principles provide the foundation for the design and implementation of the BRIDGE Center, including the policies and procedures outlined in this document. As a result of this focus on education, access, community, and innovation, this manual reflects a “living document” that will be revised on a regular basis to meet the ever-evolving demands of the neuroimaging field.

- **Co-Directors, Scientific Operations Director, & Steering Committee**

1.3 Manual Overview

We have attempted to keep this manual as concise and straightforward as possible. However compliance with federal and IRB rules, legal agreements, as well as safety, necessitates a certain level of detail in our policies and procedures. An overview of the BRIDGE Center and an opportunity to ask any questions is provided in the PI introductory meeting with the Scientific Operations Director and Co-Directors, as well as in the safety training sessions for researchers. We also encourage you to email any questions to: bridge-center@andrew.cmu.edu.

As a guide to this manual, it might be useful to keep three concepts in mind that reoccur throughout policies and procedures:

Research Projects: Projects are how the BRIDGE Center organizes research activities at the center for purposes of documentation, scheduling, and billing. Projects are defined in Section 2.2, but briefly – a project is an experiment or set of experiments that falls under one IRB protocol. Project Registration and the safety review that is part of Project Registration is a major theme of this manual. At the present time, for Pitt researchers, a project also defines the scope of an External User Agreement (EUA) which is required by Pitt and CMU administrations for Pitt users to conduct research at the BRIDGE Center.

Researchers and Research Teams: The other major set of policies and procedures in this manual refer to researchers and research teams. In order to conduct human subjects research at the BRIDGE Center researchers must complete safety training, be listed on the project IRB, and if at Pitt, be listed on the EUA.

Facilities and Safety Zones: The use of the various facilities in the BRIDGE Center including the MRI, testing rooms, mock scanner, peripheral equipment, etc. are governed by the policies and procedures in this manual. Most importantly, for safety in and around the MRI scanner, the rooms of the BRIDGE Center are assigned a Safety Zone (1 through 4) which are described in Section 3.3. Who is permitted in what Zones is dependent on training and research activity, and is referenced throughout this manual.

1.4 BRIDGE Center Personnel

Co-Directors: Timothy Verstynen, Ph.D. (CMU) & Walter Schneider, Ph.D. (Pitt)

Scientific Operations Director: John Pyles, Ph.D.

The Scientific Operations Director oversees day-to-day operations of the BRIDGE Center, provides consultation on acquisition and data analysis issues, maintain peripherals, serves as the Chair of the Safety Committee, oversees record keeping, and designs initiatives that foster community development (e.g., data sharing, tool sharing, user meetings). The Scientific Operations Director is the primary point of contact for assistance with setting up new experimental protocols at the BRIDGE Center. Contact: jpyles@cmu.edu or 412-268-3647

MRI Research Technologists: Scott Kurdilla & Mark Vignone

The MRI Technologists are responsible for the day-to-day operation of the BRIDGE Center. This includes maintaining a safe MRI center and enforcing policies, metal screening, quality assurance, scanner maintenance, scheduling, cancellations, and billing. There is one technologist present at all times. Contact:

MRI Scan Room and MR Technologists' office: 412-268-7140

Scott Kurdilla (kurdilla@cmu.edu)

Mark Vignone (vignone@pitt.edu)

Medical Director: Joseph Mettenburg, M.D., Ph.D.

Dr. Mettenburg is a neuroradiologist practicing at UPMC and is the primary consultant to the center on incidental findings of abnormalities in participants who are scanned at the BRIDGE Center. The Medical Director is also available to answer questions and consult with center staff and researchers. Contact: mettenburgjm@upmc.edu

Systems Administrator: Vincent Sha

The Systems Administrator is responsible for the functioning of the fileserver as well as the computational facilities of the BRIDGE Center. Contact: vks@andrew.cmu.edu

General Administration: Ginger Placone (gingerp@cmu.edu) & Emily Clarke (ecb27@pitt.edu)

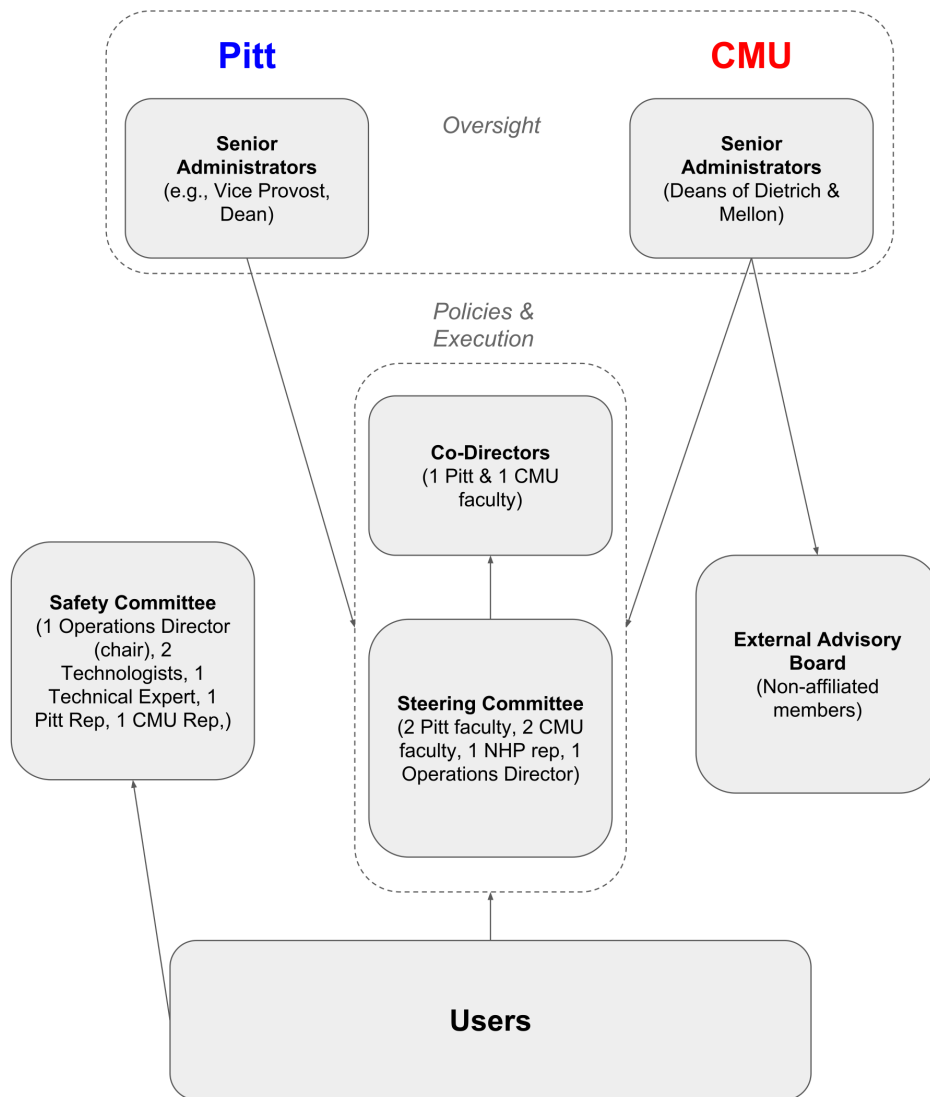
Financial Administration: Kathy Majors (km4m@andrew.cmu.edu)

Steering Committee: Drs. Julie Fiez (Chair, Pitt), David Creswell (CMU), Kirk Erickson (Pitt), Lori Holt (CMU), Brad Mahon (CMU), John Pyles (Scientific Operations Director), Robert Turner (NHP, Pitt), Gina Leckie (Pitt, Postdoc)

Safety committee: Dr. John Pyles (Chair), Scott Kurdilla (Safety Officer & Technologist), Mark Vignone (Technologist), Dr. Timothy Keller (Technical Expert), Dr. Brad Mahon (CMU), Dr. Marc Coutanche (Pitt)

1.5 BRIDGE Center Organization

Administrative Structure



Two Co-Directors, one each from CMU and Pitt, appointed by their respective Senior Administrator oversee the BRIDGE Center. Policy decisions are vetted by an 8-person cross-institutional Steering Committee (6 voting members with faculty rank, 2 non-voting members), that are appointed on an annual basis with input from the user community.

1.6 Facilities

Wean Hall

Siemens Verio 3T MRI Scanner

This is a large bore (70 cm) MR system that is designed to be more comfortable for special subject populations such as children, older subject populations, and individuals with Autism. Three head coils are available: 32 channel, 12 channel, and a transmit/receive birdcage. This scanner yields data with excellent signal to noise ratio, high stability, and excellent spatial resolution (2mm isovoxel in 2sec TR). Multi-band acceleration protocols using sequences from the Center for Magnetic Resonance Research (CMRR) at the Univ. of Minnesota (used in the Human Connectome Project) are implemented on the Verio to greatly reduce scan time while also increasing resolution in both BOLD and diffusion weighted EPI scans.

Peripheral Equipment

Detailed descriptions and how-to guides for peripherals can be found in the Peripheral Equipment Guide.

- Cambridge Research BOLDScreen MR compatible high-resolution 24 inch LCD visual display
- DLP Projector (for use with ASL eye-tracker)
- Sensimetrics S15 high-quality MR compatible audio system
- ASL Eye-tracker
- Siemens physiological monitoring (heart-rate and respiration) synchronized with BOLD protocols
- PST Response Gloves
- Other response pads

MR Suite

- Waiting room (four seats)
- Custom mock scanner with head tracking
- Large testing room
- Small testing room

Mellon Institute (to open spring 2019)

This system is a smaller bore system (60cm) that is equipped with Connectome-level gradients operating at 80mT/m. The Prisma system features new electronics including GPU based image reconstruction, 128 input channels, and optical digital-in/digital-out Direct RF. This scanner has become the standard for high quality MRI research with exceptional performance, stability, and data quality. A variety of coils are available including 20, 32, and 64 channel head and neck receive only coils, a transmit/receive birdcage coil, and a variety of standard RF coils for imaging of the spine and body. Peripheral equipment for fMRI will match the Verio system, with the addition of a high performance eye-tracker, and additional physiological monitoring capabilities.

SECTION 2: POLICIES AND PROCEDURES

2.1 Getting Started at the CMU-Pitt BRIDGE Center

Below are the steps for a new investigator who has not previously conducted a study at the BRIDGE Center. *Due to the current legal agreement between Pitt and CMU governing the BRIDGE Center, there are differences in procedures depending on if the PI and lab are at Pitt or CMU.*

For CMU PIs:

1. Contact the Scientific Operations Director, John Pyles (jpyles@cmu.edu) to setup an introductory meeting and tour, and optional meeting with the Co-Directors.
2. Read this Policies and Procedures Manual thoroughly.
3. Complete a Project Registration Application for your project (described in Section 2.2).
Note: The Scientific Operations Director is available for consultation regarding your project before you submit your application.
4. Apply for CMU IRB approval for the project.
Note: As part of Project Registration, the BRIDGE Center will conduct a safety review of your experimental protocol. The Center and Safety Committee are happy to provide help and advice if requested.
5. On receipt of IRB approval and BRIDGE project approval accounts will be setup on:
 - a. BRIDGE Scheduler System: Administered by Scott Kurdilla (kurdilla@cmu.edu)
 - b. BRIDGE Data Server: Administered by Vincent Sha (vks@andrew.cmu.edu)
6. Provide grant funding and billing information to the Scientific Operations Director (jpyles@cmu.edu) and MR Technologist (kurdilla@cmu.edu).
7. Meet with Scientific Operations Director to setup scanning protocols and equipment.

For research team members to operate at the BRIDGE Center:

- A. They must complete Safety Training. (To request email: bridge-center@andrew.cmu.edu)
- B. They must be added to your CMU IRB protocol.

For Pitt PIs:

1. Contact the Scientific Operations Director, John Pyles (jpyles@cmu.edu) to setup an introductory meeting and tour, and optional meeting with the Co-Directors.
2. Read this Policies and Procedures Manual thoroughly.
3. Complete a Project Registration Application for your project (described in Section 2.2).
Note: The Scientific Operations Director is available for consultation regarding your project before you submit your application.
4. Begin process to obtain CMU IRB approval for the project.
Note: As part of Project Registration, the BRIDGE Center will conduct a safety review of your experimental protocol. The Center and Safety Committee are happy to provide help and advice if requested.
 - a. Add the BRIDGE Center to Pitt IRB by submitting a modification to your protocol on OSIRIS.
 - i. This modification will be held pending CMU IRB approval. Once granted you will upload the approved protocol, consent, and approval letter to OSIRIS and the modification will be accepted.
 - b. Contact the CMU IRB (irb-review@andrew.cmu.edu) and initiate the approval process at CMU by obtaining an account on the SPARCS system.
 - i. You will be given a sponsored Andrew account and firewall access in order to use the online SPARCS system.
 - ii. Submit your IRB to the SPARCS system. This should **only** include procedures that will be conducted on CMU campus.
5. Begin EUA process (Instructions in Section 2.3)
6. On receipt of IRB approval and BRIDGE project approval accounts will be setup on:
 - a. BRIDGE Scheduler System: Administered by Scott Kurdilla (kurdilla@cmu.edu)
 - b. BRIDGE Data Server: Administered by Vincent Sha (vks@andrew.cmu.edu)
7. Provide grant funding and billing information to the Scientific Operations Director (jpyles@cmu.edu) and MR Technologist (kurdilla@cmu.edu).
8. Meet with Scientific Operations Director to setup scanning protocols and equipment.

For research team members to operate at the BRIDGE Center:

- A. They must complete Safety Training. (To request email: bridge-center@andrew.cmu.edu)
- B. They must be listed on and have signed the project EUA.
- C. They must be added to the project CMU IRB protocol.

2.2 Project Registration Policy and Procedures

To ensure safety, maintain thorough records, and facilitate high quality research, all research projects conducted at the BRIDGE Center must be reviewed and approved in accordance with the policies and procedures below.

Primary purpose: To ensure that experimental procedures comply with BRIDGE Center policies and practices.

Secondary purpose: To provide advice and input on developing IRB protocols and experimental procedures with regard to safety issues, and best practices for effective research.

Definition of “Project”: A project is any experiment or set of experiments that has research procedures defined by one IRB protocol. If an IRB protocol is modified with regards to experimental procedures relevant to safety or experimental procedures at the MR center, that would constitute a new project, or a new version of the project, *and would require a new safety review*. Modifications can be submitted for BRIDGE feedback before IRB submission.

Definition of “Researcher”: A researcher is any research staff who will be on premises at either of the BRIDGE Center locations and participating in human subjects research activities. All researchers must be listed on the relevant IRB protocol for the research they are conducting, have participated in Safety Training and have a Safety Training Form on file, and have signed the relevant EUA (if applicable). Researchers in training may observe as a “Visitor” (see Section 3.2).

Project Registration Approval and IRB Approval: After 11/1/18 it is strongly suggested that researchers obtain Project Registration approval *before submitting the project IRB application*. This allows any necessary revisions to experimental procedures to be made before the IRB process is started. ***Only approved Registered Projects can be conducted at the BRIDGE Center, regardless of IRB protocol approval.***

Types of Review

Expedited Review: For projects where the associated IRB protocol falls in the “Expedited” category, the project will be reviewed and approved by the Scientific Operations Director or a person designated by the Scientific Operations Director. The targeted turnaround time for an Expedited Review is 5 business days or less.

Full Review: Projects where the associated IRB protocol falls into the “full board” category will be reviewed and approved by a quorum of the full Safety Committee. Full Safety Review may also be required if a project introduces experimental procedure that is new to the center, a new piece of experimental equipment, involves a high risk population, or if there is an experimental procedure the Scientific Operations Director feels requires the input of the full committee. The targeted turnaround time for an Full Safety Review is 10 business days or less.

Project Registration Instructions

1. Assemble a Project Application Packet.

Contents:

- I. Project Application Form (Appendix B)
- II. IRB Protocol Text (*Either draft text which is preferred, or submitted or approved text. Make a pdf from the “View Printer Version” in CMU SPARCS and also attach any additional document you have included such as draft consent form, screening form, equipment description, etc.*)
- III. Additional notes or explanations of procedures (*optional*).
- IV. Safety procedures for any new equipment or atypical experimental methods (*if necessary*).

Note: The Scientific Operations Director is available for consultation and advice to assist with any aspect of the Project Application packet.

2. Submit the Project Application Packet to the Scientific Operations Director, John Pyles via email (jpyles@cmu.edu).

3. If the research group is from Pitt (or other non-CMU institution), the Scientific Operations Director will return an External User Agreement (EUA) to the PI to begin the EUA process. Follow the EUA instructions in Section 2.3.

4. The Application Packet undergoes either Expedited or Full Review as defined above. *If necessary:* Comments are returned and the application is revised.

5. Application is approved.

6. Protocol text is submitted for IRB approval (if not already approved).

7. After IRB approval, submit the following to Scientific Operations Director:

- I. IRB approval letter
- II. Full approved IRB protocol text *including study team members (make pdf from “View Printer Version” in SPARCS).*
- III. Copy of approved Consent Form

If necessary: Scientific Operations Director reconciles any differences in submitted protocol text and approved protocol text.

***If an EUA is necessary:* Scientific Operations Director submits Pitt signed EUA and IRB approval to CMU OSP for CMU signature.**

8. **Scientific Operations Director or a Co-Director signs and approves the Project for scanning at the BRIDGE Center.** The approved Project Registration Form is kept on file and a copy returned to the PI.

Project Registration Form Field Information

- *Project Name:* The full name of the project which should match the IRB protocol title.
- *Project Short Name:* A 1-3 word name for the project for use in the BRIDGE Center scheduling system.
- *Lab/Research Group Name:* This name will be used for your lab/research group in the BRIDGE Center online scheduler.
- *Office Location:* Physical office location (not mailing address).
- *Office Phone:* Normal business phone for PI.
- *Mobile (emergency) Phone:* Best phone number for emergency contact.
- *Primary Project Contact:* The lead researcher with respect to scanning participants at the BRIDGE Center. Usually whichever researcher will be conducting most of the scans (PI, grad student, RA, postdoc).
- *Billing Contact:* The lab member in charge of finances and billing with respect to the BRIDGE Center (PI, RA, lab manager, grant manager, etc.)
- *Project Team Members:* Lab members who will be participating in the research project with regards to MR scanning at the BRIDGE Center. “Position” is the person’s position in the lab (grad student, RA, postdoc, research staff, etc.). “Role” is the person’s role in the project: “Researcher” indicates the person will be conducting research activities in the BRIDGE Center. “Recruiter”, “Screener”, “Admin”, etc. would indicate a role involved with MRI scanning tangentially, but not conducting research activities on site at the BRIDGE Center. Those who are “Researcher” must have completed BRIDGE Center Researcher Safety Training and be approved Researchers at the center.
- *BRIDGE Center Use:* This section of the form will be used for approval signatures and tracking purposes for IRB protocol and EUA protocol (for Pitt or non-CMU PIs).

2.3 External User Agreements

At the current time users from the University of Pittsburgh or other non-CMU institutions must complete an External User Agreement (EUA) in order to scan at the BRIDGE Center. The EUA is a contract between the institutions addressing liability and other issues.

External User Agreement (EUA) Instructions

These are instructions for obtaining an External User Agreement (EUA) to operate as a non-CMU affiliated user at BRIDGE Center. **This EUA process should be completed as Step 3 of the Project Registration process after the Project Application Packet has been submitted to the Scientific Operations Director, John Pyles (jpyles@cmu.edu).**

⇒ Questions and help on the Pitt side EUA Process email Emily Clarke (ecb27@pitt.edu).

1. After receiving the Project Application Packet, John Pyles will return an External User Agreement (EUA) to the project PI for completion and Pitt signatures. Do not amend any old or existing EUA forms. Each EUA is generated and tracked by the BRIDGE Center.
2. The Project Registration process should continue with submission of a CMU IRB protocol application. CMU Office of Sponsored projects requires having CMU IRB approval to sign the EUA after Pitt has signed.
3. Complete the External User Agreement document.
 - a. "Title of Study" will be filled in by John Pyles before he sends the EUA. (A# will be added by CMU.)
 - b. Fill in "Effective Date" and "End Date" (EUAs can be up to two years).
 - c. Fill in "Description of Work" (Attachment 1). The "Description of Work" should be one to a few paragraphs describing the research that will be conducted at the BRIDGE Center study only. A brief description of the purpose the number of subjects and sessions, etc.
 - d. Obtain signatures for all users: **PI and all researchers staff (defined as "Researchers" in Section 2.2) who will be on premises at Wean Hall participating in human subjects research will need to sign the agreement. Please use multiple copies of the signature form on the back if you need more lines.**
4. Fill out the Sole Source Justification Form (<https://cfo.pitt.edu/pexpress/forms.php>)
 - a. Choose "The requested product or service is essential in maintaining continuity in the following manners"
 - b. Check "this good/service has been identified and approved in this research grant contract" and enter grant source and number.
 - c. Have the PI sign the "requestor" line
5. Fill out the Contact Entry form (<https://cfo.pitt.edu/pexpress/forms.php>)
6. Submit a request for a certificate of insurance here:
<https://apps.fis.pitt.edu/cfoforms/CertificateOfInsurance/Create>
 - a. Apply for General Liability
 - b. Name John Pyles as the CMU recipient for a receipt of the certificate
352 Baker Hall, Pittsburgh, PA 15213
jpyles@cmu.edu
(412) 268-3647
7. Save all docs from steps 1-4 (the certificate of insurance should be processed within 24 hours and will be emailed to you as a PDF).
8. Log onto Panther Express and create a new requisition using the Supplier Provided Agreement form. **You must have a Panther Express account to do this** (if you don't, you must request one here: <https://cfo.pitt.edu/pexpress/pbuyuser.php>). The **Departmental Post-Award fiscal staff** (Brad Hyland – LRDC, Shelley Dubovecky – Psychology, John Jene – Psychiatry, *contact info*

below) via a Requisition using the Supplier Provided Agreement Form on Panther Express needs to push it through to Procurement.

- a. In the comments section of the form, type that the fiscal staff needs to provide the following in writing / comments to the Procurement Specialist (Cole Kurtz – LRDC, Molly Scott – Psychology, John Jene – Psychiatry).
 - i. Title of the EUA
 - ii. PI on EUA (or Amendment)
 - iii. Primary Pitt Contact for EUA Questions (Researcher)
 - iv. Start Date of the Agreement
 - v. End Date of the Agreement
 - vi. Current Providers Fee for the Agreement (Example: Provider’s Fee is \$460.00 per hour for use of the MRI scanner)
 - vii. Request that the above information / list and the final Pitt signed EUA be sent directly to John Pyles at jpyles@cmu.edu
 - viii. Request that Primary Pitt Contact also be cc’ed at <your email> email address on the email to John Pyles

REMINDER: The submission by the fiscal staff to the Procurement Specialist must include the following attachments

1. Signed EUA from Lab (basically anyone who will step foot on CMU property)
 2. Sole Source Justification Form
 3. Contract Entry Form
 4. Insurance Certificate
9. Email the Pitt signed EUA to John Pyles (jpyles@cmu.edu). **Do not submit an EUA directly to CMU Office of Sponsored Programs (OSP).**
 10. When CMU IRB Approval is received, return to Step 7 of the Project Registration process to submit IRB documents to John Pyles (jpyles@cmu.edu).
 11. John Pyles will submit the Pitt signed EUA and IRB approval to CMU’s OSP to obtain the CMU signatures/approval of user agreement. Once the agreement is executed (approximately 2 weeks), John Pyles will send the signed agreement to the external PI for their records as part of Step 8 of Project Registration.

Once the Project Registration process is complete, the Scientific Operations Director will help coordinate scheduling, computer accounts, and final preparations to begin your study.

Key Contacts and Personnel for EUA Process

⇒ Questions and help on the Pitt side EUA Process email Emily Clarke (ecb27@pitt.edu).

University of Pittsburgh

IRB

Email: askirb@pitt.edu

Linda Banks, Administrative Assistant

412-383-1480 | ljb47@pitt.edu

Procurement / Panther Express

Email: EChelp@pitt.edu

Website: <https://www.export.pitt.edu/procedures/procurement>

Allen DiPalma, Director

412-624-7415 | dipalma@pitt.edu

LRDC: Cole Kurtz, CQE, C.P.M. Procurement Specialist

4-6079 | ckurtz@cfo.pitt.edu

Psychology: Molly Scott, CPSM Procurement Specialist

4-6204 | msscott@cfo.pitt.edu

Psychiatry: John Jene, Procurement Specialist

4-1747 | jjene@cfo.pitt.edu

Full list of staff and department assignments:

<https://www.cfo.pitt.edu/pexpress/documents/PurchasingServicesStaffDirectory.pdf>

Fiscal Staff

Panther Express General Phone:

412-624-3578

LRDC: Brad Hyland, Fiscal Specialist

4-7027 | hyland@pitt.edu

Psychology: Shelly Dubovecky, Sponsored Projects Admin

4-4529 | shelly.dubovecky@pitt.edu

Psychiatry:

Carnegie Mellon University

IRB

SPARCS, Help Desk: 412-268-3485 | SPARCS-HELP@andrew.cmu.edu

Website: <https://www.cmu.edu/research-office/sparcs/>

IRB General: Help Desk: 412-268-7166 | irb-review@andrew.cmu.edu

Website: <https://www.cmu.edu/research-compliance/human-subjects-research/contact.html>

Teri Reiche, Director IRB & IACUC

412-268-5460 | treiche@andrew.cmu.edu

2.4 Adding Additional Personnel

Compliance with BRIDGE Center policies and governance agreements requires that Principal Investigators authorize new researchers (as defined in the Project Registration Policy) to conduct research activities for a project at the center. This policy is to ensure that personnel conducting human subjects research at the BRIDGE Center are covered by a current IRB protocol, authorized to conduct research on behalf of a PI, and to track BRIDGE Center Safety training. At the current time, PIs with an External User Agreement (EUA) are required to add all new researchers who will participate in research activities at the BRIDGE Center to their EUA. This is to ensure researchers are covered by the protections of the EUA.

Procedure for Adding Research Personnel

1. **Principle Investigator adds the new researcher to their CMU IRB personnel by doing a IRB protocol modification using SPARCS.**
2. ***Pitt or external PIs: Principle Investigator completes EUA Amendment.***
 - a) New researcher(s) sign the EUA Amendment (can be obtained from John Pyles).
 - b) PI obtains Pitt institutional signature on EUA Amendment.
 - c) PI emails the Scientific Operations Director the Pitt signed EUA Amendment.
 - d) John Pyles forwards Pitt signed EUA Amendment to CMU OSP for counter-signature.
3. **Principle Investigator emails the Scientific Operations Director (John Pyles, jpyles@cmu.edu) authorizing the new researcher to conduct research activities for a specific project.**
 - a) **PI should include a pdf copy of the IRB modification approval letter which should include the new researchers name.**
4. **New researcher completes BRIDGE Center Researcher Safety Training.**
5. **Scientific Operations Director adds the new Researcher to the Project Registration form and returns a copy to the PI along with the CMU signed EUA Amendment (if applicable).**

2.5 Fees

The main goal of the fee schedule is to produce revenues that offset operating costs. The hourly fee has been arrived at by dividing the projected annual operating cost by the estimated number of hours of usage and adjusted for estimated inflation of costs across time. A key tenet of a re-charge center under the OMB mandate that governs university accounting practices is that all users or funding sources are treated equally. No one can get a price break or free hours unless the opportunity is open to all users.

Scanning Fee: The fee for all CMU and Pitt investigators is updated annually, with the goal of keeping fees relatively stable and affordable to center users without sacrificing critical research support. The latest projected fee schedule for CMU and University of Pittsburgh investigators is attached as Appendix A to this document and available on the BRIDGE Center’s website. The fee for researchers at institutions other than CMU and the University of Pittsburgh is determined during the negotiation of External User Agreements with the Office of Sponsored Projects at CMU

Pilot hours: The BRIDGE Center is continuing the previous SIBR policy of providing support for pilot scanning time that is earned by a grant or funding source with the purchase of paid time, at a rate of 30 pilot minutes per paid hour, up to a maximum of 20 pilot hours per year, per grant. The pilot time is assigned by the BRIDGE Center between 9:30 am and 9:00 pm Monday-Saturday, in consultation with the investigator, during periods of lower paid usage. The pilot hours may not be used for the regular studies intended for inclusion in a publication, but are intended for scientific exploration of grant-related issues. These pilot hours expire one year after the grant has ended. Pilot studies like all other studies need IRB approval, which in many cases might be covered by the project’s existing IRB protocol.

2.6 Scheduling

Scheduling policies are determined by the Steering Committee, based on input from users and the BRIDGE Center staff. The scheduling policies will be reviewed by the Steering Committee at least twice per year.

Scheduling Ethos: The scheduling policies of the BRIDGE Center are based on maximizing research output, not revenue. Facilitation of great research is a community effort. BRIDGE Center users are expected to conduct their research in a courteous manner, considerate of other researchers, especially with regards to scheduling hours and staying on schedule.

Scheduling Policies:

- Slots are open for reservation five weeks in advance on the online scheduler.
- The shortest time slot that can be scheduled is 30 minutes.
- If there is a schedule gap between two scans from the same research group, it should be at least one hour so as to allow reasonable time for others to use scanner. Requests for exceptions to this policy should be discussed with the Scientific Operations Director and Co-Directors. Back to back scans from the same research group are completely acceptable.
- There should be a confirmed participant for the time slot before it is scheduled.

Cancellations: In keeping with the ethos above, ***there are no fees or penalties for cancelling a timeslot.*** Scans that are ended before completing their scheduled timeslot (e.g. a subject withdraws early from a scan session) will incur the fee for the time used in 30min increments. Users are reminded that last minute cancellations and early termination of sessions results in time that cannot be used by other researchers. Records of cancellations and early terminations,

including the reasons when available, will be kept and reviewed by the Co-Directors, Scientific Operations Director, and Steering Committee four times a year. In cases of excessive cancellations or early terminations that impact other researchers ability to use scanner time, the Steering Committee may impose scheduling restrictions or conditions on the research group.

Pre-Reserved Timeslots: In the circumstance that a study needs to follow a specific scanning timeline, or if there are special considerations with scheduling the participant population, timeslots can be held ahead without a confirmed participant. To arrange for Pre-Reserved Timeslots, please contact the Scientific Operations Director, John Pyles, (jpyles@cmu.edu).

Best Practices: To avoid unnecessary cancellations and facilitate the best use of scanner time, researchers should follow these best practices:

- There should be a confirmed participant for the time slot before it is scheduled.
- The participant should be pre-screened by the research group before being scheduled to avoid last minute cancellations due to MRI contraindications. (See provided pre-screening sample questionnaire.)
- The scan time should be confirmed with the participant prior to the session, and the participant should be re-screened for any last minute contraindications (e.g. cold, cough).
- The participant should be asked to arrive at least 10-15 minutes before the scheduled scan time.
- If a timeslot is cancelled *less than 7 days* before a scan, the scheduling email list should be notified to allow the time to be used by another research group.

Keeping on Schedule: *Researchers are expected to fully complete their scanning session at the end of the scheduled timeslot.* This means the subject is out of the scanner, experimental computers and equipment are restored to their normal states, and the next research group can begin their setup and scan. *If the scan session time exceeds the time allocated in the reserved slot, an additional half hour of scan time will be charged.*

2.7 Shakedown Scans & Technical Development

Shakedown Scans

A very small number of scans, also known as “shakedown” scans, are offered for investigators to test a new protocol(s) or equipment during normal scan hours, in an actual scanning situation with your MRI paradigm. The shakedown time is assigned by the BRIDGE Center between 9 am and 9 pm, in consultation with the investigator. Contact Scott Kurdilla (kurdilla@cmu.edu) to schedule shakedown scans.

Technical Development and Pulse Sequence Testing

Investigators who are developing new techniques not for publication but for future research use may be offered technical development time. Pulse sequence and other technical testing require IRB and BRIDGE Center Safety Committee approval. The technical development time is assigned by the BRIDGE Center between 9 am and 9 pm, in consultation with the investigator. Contact John Pyles to setup technical development time.

New users or experienced users with new projects should consult with the BRIDGE Center's Scientific Operations Director, John Pyles, (jpyles@cmu.edu) to set up MR sequences and scanning parameters.

2.8 Computer Accounts

BRIDGE Center investigators and their research staff will need accounts on two machines: one for scheduling and one for retrieving data files.

To request accounts please email the Scientific Operations Director (John Pyles, jpyles@cmu.edu).

Scheduler

Web Address: <https://schedule.sibr.cmu.edu/>

Administrator: Scott Kurdilla (kurdilla@cmu.edu)

File Server

SFTP access: `fileserver2.sibr.cmu.edu` (port 33)

Administrator: Vincent Sha (vks@andrew.cmu.edu)

2.9 Data Retrieval

Soon after the completion of a research scan, the data are uploaded onto the BRIDGE Center fileserver (`fileserver2.sibr.cmu.edu`). Data files can be retrieved via SFTP or SCP. **Data files are guaranteed to be kept on the fileserver for two weeks.** After two weeks, the images may no longer be available. It is highly recommended that users retrieve and check their images as soon as they are available on the fileserver.

2.10 Participant Information and Data De-Identification

- ⇒ As a formal policy, the BRIDGE Center does not record or retain linking information between data collected at the center and participant identity. All MRI data collected is de-identified.

Participant Information

The BRIDGE Center will scan and securely retain copies of the signed consent form, and the MRI Safety Screening form. The Session ID is not recorded on these documents and therefore the BRIDGE Center does not record any linking information between a participant's name and their Session ID.

MRI Data De-Identification

Participant names are not entered into the MRI console or recorded in the MRI data (DICOM) header information. The Bridge Center assigns a session identification number to each MRI session based on the time and date the participant was registered in the MRI console. The Session ID will be saved in the Patients Name (0010,0010), and PatientID (001,0020) fields of the DICOM header. The participant's birth date is entered into the console as January 1st, year of birth, and will be saved in the PatientsAge (0010,1010) field. Exact birth dates are not saved. Participant sex and weight are also entered into the console and saves in the DICOM header respectively in PatientsSex (0010,0040) and PatientsWeight (0010,1030) fields. The name of the PI and MRI protocol folder are also saved.

Note: Anatomical MRI data (e.g. MPRAGE scans) are generally not considered to be de-identified since fairly high resolution facial data is retained in the scan. Before sharing data publicly or outside those authorized access in your IRB protocol, consider “de-facing” anatomical MRI scans. Useful tools for this are *pydeface* and *mri_deface*.

2.11 Providing Brain Images to Participants

The BRIDGE Center does not print or provide brain images to participants. Management and distribution of data collected at the center is the responsibility of researchers and governed by their IRB protocol. If researchers would like to give brain images to participants, provisions should be made in the study IRB protocol to do so.

SECTION 3: SAFETY POLICIES

3.1 Introduction and Organization

The purpose of this section is to provide a resource for continued safe MRI practices within the BRIDGE Center research community. All BRIDGE Center users should be familiar with these operating and safety practices. Magnetic Resonance Imaging (MRI) related injuries and fatalities have occurred when there was an apparent failure to follow safety guidelines. It is required that all BRIDGE Center researchers complete safety training prior to obtaining access to the MRI environment.

Organizational Safety Policies

- I. The CMU-Pitt BRIDGE Center will maintain MR Safety Policies and Procedures, which are to be established, maintained, and routinely reviewed by the Safety Committee.
- II. The policies and procedures shall be reviewed and updated semi-annually. Introduction of any significant changes in MRI system hardware or software that will significantly change the safety parameters in the MR imaging environment (e.g. adding faster/stronger gradient capabilities, higher RF duty cycle sequences), will be reviewed by the Safety Committee prior to implementation. In this review process, national and international standards and recommendations should be taken into consideration prior to establishing our own local guidelines, policies, and procedures.
- III. It is the responsibility of the Safety Committee to ensure that the MRI safety guidelines are established and maintained on a current basis.
- IV. Procedures should be in place to ensure that all adverse MRI safety events that occur in the MR center are reported to the Chair of the Safety Committee in written form (incident report) within 24 hours.
- V. All incidents and adverse effects will be discussed at a quarterly meeting of the Safety Committee. A serious adverse event will result in an immediate session of the Safety Committee.

Safety Committee

Current Members:

Dr. John Pyles, Committee Chair
Scott Kurdilla, Safety Office & MR Technologist
Mark Vignone, MR Technologist
Dr. Timothy Keller, Technical Expert
Dr. Bradley Mahon, CMU User Representative
Dr. Marc Coutanche, Pitt User Representative

3.2 Core Safety Policies

1. **Before anyone (staff, subject, visitor) may enter the magnet room (Zone 4), a screening form must be completed and reviewed by the MRI Operator.** For persons who are employed by the Center, the form should remain on file at the center, reviewed annually, and updated immediately with any changes that are contra-indications for the MRI environment. Subjects who return for another MRI exam must fill out a new screening form each time they visit or review an existing screening form on file. The screening form must be signed by the subject and the MRI Operator who is performing the scan.
2. **All persons conducting research activities in Zone 3 or Zone 4 must have completed BRIDGE Center Researcher Safety Training.**
3. **A signed consent form must be presented before a participant can enter the magnet room (Zone 4).**
4. **Before entering the magnet room (Zone 4), everyone must remove from their person and clothing any possible projectile metallic objects and loose items.**
5. **When there is a person in the magnet, at least two other safety trained individuals must be present in Zone 3 or Zone 4: a MRI Operator, and a safety trained researcher able to enter the magnet room (Zone 4). This is the “Two Person” Rule.**
6. **The magnet room (Zone 4) door should be kept closed at all times except when entering or exiting the room.**
7. **All persons scanned or in the Magnet Room while the scanner is operating must wear proper ear protection.**
8. **No objects (regardless of MR compatibility) shall be taken into the magnet room (Zone 4) when a person is in the magnet bore. All research related equipment and objects must be in the magnet room before anyone is put into the magnet bore.**
9. **Use of any research equipment, coils, or supplies not supplied by the BRIDGE Center must be approved by the Safety Committee with documented safety protocols and procedures.**

3.3 Safety Zones

The BRIDGE Center is divided into four safety zones based on the American College of Radiology system for safety zones in an MRI facility. **Researchers in the BRIDGE Center should always be aware of what MRI Safety Zone they are currently in, and what restrictions and rules apply for that Zone.**

Zone 1: Public areas with unrestricted access. (Hallway outside the BRIDGE Center.)

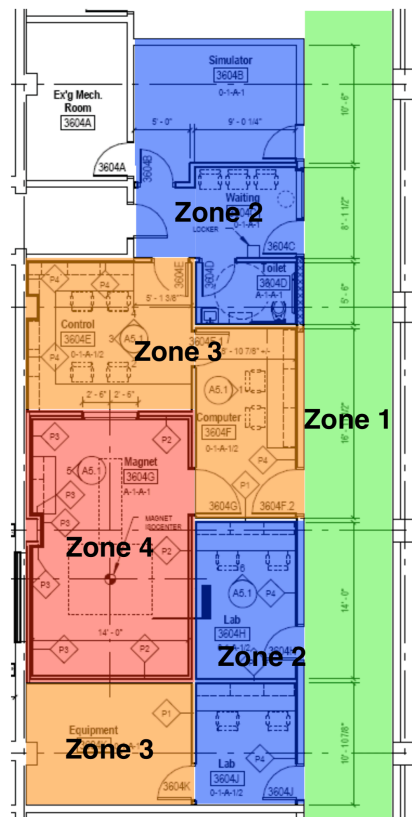
Zone 2: Interface between public areas and restricted areas (waiting room, mock scanner, behavioral testing rooms) where research testing is done and MRI screening is conducted. Visitors and volunteers do not require an escort in Zone 2.

Zone 3: Restricted area. All visitors and volunteers in Zone 3 (control room, vestibule, and equipment rooms) *require escort by authorized personnel* to enter this zone.

- ⇒ Volunteers should be screened before entering Zone 3.
- ⇒ Volunteers *must* be screened before entering the vestibule.

Zone 4: Highly Restricted Area! MRI Magnet Room. All persons entering Zone 4, including researchers, volunteers and special visitors must fill out and sign an appropriate screening form.

- ⇒ Absolutely No Admittance without proper screening and escort by authorized personnel (Technologist or Level 3 personnel).



3.4 Personnel Categories & Safety Training

The BRIDGE Center 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. This category also includes individuals being scanned for the purposes of testing scanner protocols or equipment who must also sign a consent form.

- Must have signed an IRB approved consent form to participate in an MRI scan or research protocol.
- Must have a signed and complete MRI Screening Form approved by an MRI Operator to enter Zone 3 or Zone 4 (Magnet Room).
- Must always be accompanied and supervised in Zone 3 or Zone 4 by an MRI Operator.

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

- Must have a signed and complete MRI Screening Form approved by an MRI Operator to enter Zone 3 or Zone 4 (Magnet Room).
- Must always be accompanied and supervised in Zone 3 or Zone 4 by an MRI Operator.
- May not consent volunteers at the BRIDGE Center or directly participate in human subjects research.

Basic Researcher (Level 1): Not currently in typical use at the Wean Verio. New researchers should be Level 2 safety trained.

Requirements:

- Have attended the Basic Safety Training Class or online class or equivalent class approved or received one on one training from the Safety Officer or Scientific Operations Director.
- Is listed on an approved and current IRB protocol and EUA (if applicable).

Wean Privileges:

- Escort subjects to waiting room.
- Enter the control room without requiring MRI Operator permission.
- Access to testing rooms and Mock Scanner.
- Assist with consent and screening of subjects.

Researcher (Level 2): This is the typical safety training level for researchers running studies at the BRIDGE Center. Individuals must have Level 2 training to conduct studies at the BRIDGE Center as the “second person” with an MRI Operator.

Requirements:

- Have attended the Safety Training Class or received one on one training from the Safety Officer or Scientific Operations Director.
- Have passed the Safety Quiz.
- Have a complete MRI Screening Form approved by an MRI Operator on file.

- Is listed on an approved and current IRB protocol and EUA (if applicable).
- Have a MRI Researcher authorization form signed by the Safety Officer, Scientific Operations Director, or Co-Director on file.
- Is trained to assist the MRI Operator in an emergency situation and able to enter the Magnet Room (Zone 4).

Wean Privileges:

- Access to testing rooms and Mock Scanner.
- Assist with consent and screening of subjects.
- May enter the control room without requiring MRI Operator permission.
- May enter the Magnet Room (Zone 4).
- May conduct studies alone with the MRI Operator. (Be the “second person”.)

MRI Operator (Level 3): Individual who is approved to run the MRI console and fulfill the responsibilities of the MRI Operator defined above.

- *Currently MR Center Staff Only:* Technologists, Scientific Operations Director, Technical Manager

Safety Level Training Transition Period

A transition period is provided to allow researchers who have completed the previous safety curriculum for scanning on the Wean Verio to fulfill the new MRI Researcher (Level 2) requirements. Researchers who have completed the previous safety training or safety training at NIC are considered Level 1 Basic Researchers, but continue to retain their current privileges during the transition period.

- The researcher will complete an MRI Screening Form the next time they are at the BRIDGE Center in Wean Hall.
- By April 1st, 2019 the researcher will complete updated training curriculum either by attending a Safety Training Class or receiving one on one training from the Safety Officer or Scientific Operations Director.

3.5 MRI Safety Screening

⇒ **Before anyone (staff, subject, visitor) may enter the magnet room (Zone 4), a screening form must be completed and reviewed by the MR Operator.** For persons who are employed by the Center, the form should remain on file at the center, reviewed annually, and updated immediately with any changes that are contra-indications for the MRI environment. Subjects who return for another MRI exam must fill out a new screening form each time they visit or review an existing screening form on file. The screening form must be signed by the subject and the MR Operator who is performing the scan.

The importance of the MRI safety screening procedure cannot be overstated.

Metal Screening Research Participants

It is mandatory for every research participant to undergo comprehensive screening in preparation for an MRI study. Comprehensive screening involves the use of the standard screening form (Appendix C) to document the screening procedure, a review of the information on the screening form, and an oral interview by the MR Operator to verify the information and allow discussion of any question or concern that the research participant may have. The MRI Safety Screening form must be reviewed and signed by the MR Operator. It should be noted that having undergone a previous MRI procedure without incident does not guarantee a safe subsequent MRI examination. Various factors (e.g., static magnetic field strength of the MR scanner system and orientation of a metallic implant or object) can substantially change the scenario. Therefore, a comprehensive screening procedure must be conducted every time a research participant prepares to undergo an MRI procedure. This is not an inconsequential matter, because a seemingly unrelated event may have occurred that could affect the safety of the research participant entering the MRI environment. Details of MRI screening and MRI contraindications are found in Section 5.

Implants and Devices

Implants and devices are evolving rapidly and must be thoroughly investigated if potential participants or individuals who will enter the magnetic environment indicate their presence. If the individual knows or has documentation as to the specific manufacturer and type of device, then the following steps are implemented:

- Look up the item by the manufacturer in the current *Reference Manual for Magnetic Resonance Safety, Implants, and Devices* by Frank G. Shellock, Ph.D. or on the web site: <http://www.mrisafety.com>
- If the implant or device is listed as “Safe” at 3T, it is okay to scan.
- If the device or object is not listed there or has not been tested at 3 Tesla, then contact the manufacturer for the following information and written documentation:
 - Have the manufacturer fax the text that states the device is MRI safe and at which magnetic field strength(s), and conditions, it is safe.
- If a study participant has an implant or device of unknown model or manufacturer, the project PI should contact the Safety Committee Chair (John Pyles, jpyles@cmu.edu), to discuss possible accommodation or special procedures.

3.6 Equipment & Objects in Zone 4 (Magnet Room)

- ⇒ **No research equipment or objects are permitted to be brought into the Magnet Room (Zone 4) without authorization by the MR Operator and/or BRIDGE Center Safety Committee.**

Any object taken into the Magnet Room must be approved by a MR Technologist, the Scientific Operations Director, Technical Manager, or Co-Director.

Experimental Equipment: Any experimental equipment or device not provided by the BRIDGE Center to be used in a research project must be approved by the BRIDGE Center Safety Committee as part of the “Full Review” during the Project Registration process. The Safety Committee will typically require:

1. A detailed standard operation procedure (SOP) for how the equipment is to be used during the research project.
2. Documentation of MRI compatibility if the equipment will enter the Magnet Room.
3. Any emergency procedures that would be associated with the use of the equipment.

⇒ **No object (regardless of MRI compatibility) shall be brought into the Magnet Room when there is a person in the magnet bore.**

When there is a person in the magnet bore there is the greatest risk of injury from the “projectile effect” from a non-MRI compatible object introduced to the MRI environment. Thus no objects shall be brought into the Magnet Room while there is a person in the magnet bore. This is regardless of MRI compatibility or approval of an object or equipment to enter the magnet room. All research equipment should be in the magnet room prior to the participant being put into the bore. The exception to this rule shall be in an emergency situation where the MRI Operator may authorize MRI compatible equipment needed in the Magnet Room to address the emergency.

3.7 The “Two Person” Rule

⇒ **When there is a person in the magnet, at least two other safety trained individuals must be present in Zone 3 or Zone 4: a MRI Operator, and a Level 2 safety trained researcher able to enter the magnet room (Zone 4). This is the “Two Person” Rule.**

To be able to adequately deal with an emergency situation and follow safety protocols, two people are necessary. Thus when someone is in the MRI two people must always be in the Control Room (Zone 3) or Magnet Room (Zone 4). One person should be the MR Operator (usually the Technologist), and the other a researcher with Level 2 safety training and no contraindications for entering the Magnet Room. The researchers should assist and follow the instructions of the MR Operator in an emergency situation.

3.8 Pregnancy

⇒ **As standard practice, pregnant individuals are not approved to be scanned in the MRI at the BRIDGE Center.**

Exceptions may be granted contingent on review and approval of the research protocol by the full board IRB, full Safety Committee, and Co-Directors.

Screening: Individuals are screened for pregnancy as part of the MRI Safety Screening form which is signed by the person being screened and the MR technologist conducting the screening. Individuals who respond “Yes” to the question “Are you pregnant?” on the MRI Safety Screening form are *not approved* to be scanned in the MRI unless they are a participant in a research protocol that meets the exception criteria above. *The BRIDGE Center does not provide or conduct pregnancy tests.* In the circumstance that a pregnancy test is part of an IRB protocol, the test must be maintained and administered by the researchers in accordance with their IRB protocol. BRIDGE Center staff should not be provided information about the results of pregnancy tests.

MR Environment: Individuals who are or may be pregnant are not allowed to remain in the Magnet Room (Zone 4) while the RF and gradients are operating. Pregnant individuals may remain in the Control Room (Zone 3) and enter the Magnet Room between scans, during a study. This includes staff or individuals accompanying the research participant.

3.9 Incidental Findings

It is the Principal Investigators’ responsibility to take appropriate action if an incidental finding (unexpected brain abnormality) is detected. To facilitate the investigators’ actions and provide information to the subject, the BRIDGE Center has arranged for the services of a Medical Director with neuroradiology expertise who will advise the PI of his assessment of the incidental finding. The following procedures should be followed:

If the MR Technologist or researcher identifies an unexpected brain abnormality during the scan of a subject:

1. The MR Technologist will perform the scan without informing the subject or the subject’s parents or family to avoid causing alarm.
2. An email will be sent by the MR Technologist to the PI conducting the study, the researcher conducting the scan, the Chair of the Safety Committee (Scientific Operations Directory) and to the Medical Director describing the case.
 - a. The Safety Officer (Scott Kurdilla) will archive all cases.
3. The MR Technologist will provide the scan(s) to the Medical Director (Dr. Joseph Mettenburg).

4. The Medical Director will review the scan(s), and then send his/her conclusion/assessment of the finding to all the individuals identified above. He will make one of the following assessments:
 - a. The incidental finding is non-significant, and no action is needed. Case Closed.
 - b. The incidental finding is non-significant, but the subject should be made aware that an incidental finding was made.
 - i. The PI should inform the subject
 - ii. The subject should be informed the Medical Director is available to answer any questions and/or consult with their medical care team.
 - iii. A concluding email detailing the actions that took place to inform the subject should be sent to the technologist who conducted the scan and Safety Committee Chair by the PI.
 - iv. Case Closed.
 - c. The incidental finding is significant and the subject needs to be informed.
 - i. The PI should inform the subject
 - ii. The subject should be informed the Medical Director is available to answer any questions and/or consult with their medical care team.
 - iii. A concluding email detailing the actions that took place to inform the subject should be sent to the technologist who conducted the scan and Safety Committee Chair by the PI.
 - iv. Case Closed.

In the very rare case of a pressing emergency, the MR Technologists will advise the subject that an incidental finding was made and suggest that they admit themselves to the emergency room as soon as possible.

After a case is closed, the Safety Officer responsible for archiving incidental findings (Scott Kurdilla) manages the record-keeping so that cases can be pulled for future statistical review. Confidentiality will be maintained at all times throughout these procedures.

3.10 Pre-Screening

- ⇒ **Participants in MRI studies at the BRIDGE Center should be pre-screened by the lab conducting the study before they are confirmed to schedule a scan.**
- ⇒ **Researchers who pre-screen participants in person or by phone are strongly recommended to have Level 1 and preferably Level 2 BRIDGE Safety Training.**

Pre-screening subjects is an important process for the safety of the subject, and efficiently running the BRIDGE Center and conducting research. Participants who are not properly pre-screened might arrive for a scan with a contraindication for MRI causing the scan to be cancelled.

Subjects should be pre-screened before a scan session is scheduled. This pre-screening should cover both exclusion criteria for participating in an MRI such as having a pacemaker or non-removable piercing, and also cover any research specific requirements for the study such as handedness, color blindness, etc.

The BRIDGE Center provides a sample set of pre-screening questions in Appendix D that cover both exclusion criteria for safety, and common exclusion criteria for data quality or experimental reasons. These questions should be customized by researchers for their specific project, and formatted either as a paper form, in person or phone interview script, or secure online questionnaire such as Qualtrics. The pre-screening questionnaires should be submitted as part of supporting documentation for Project Registration at the BRIDGE Center, and also as part of the IRB Protocol for a study.

3.11 Ear Protection

- ⇒ **All persons scanned or in the Magnet Room while the scanner is operating must wear proper ear protection.**

The BRIDGE Center provides earplugs of various sizes for ear protection while being scanned. Earplugs should be properly inserted as described in Section 5. The Sensimetrics S15 earphone system provides ear protection when properly used following the Sensimetrics SOP and safety protocol.

3.12 Clothing

- ⇒ **It is strongly suggested that subjects be advised to wear comfortable, all natural fiber (cotton, wool, linen, etc.) clothing for their scan.**
- ⇒ **Anti-microbial athletic wear containing silver fibers cannot be scanned in the MRI due to risk of heating.**

Participants at the BRIDGE Center are not required to change clothes or wear scrubs to be scanned. However, to reduce the risk of doubt about the MRI safety of a particular material and potential delays due to participants needing to change clothing before scanning, it is strongly suggested that subjects be advised to wear comfortable, all natural fiber (cotton, wool, linen, etc.) clothing for their scan. Some clothing materials (usually athletic wear) labeled as anti-microbial contain silver fibers. There is a risk that these materials can heat during an MRI scan and cause burns. Therefore any clothing suspected of containing silver fibers cannot be scanned in the MRI. These materials can be difficult to identify as there is no comprehensive list of brands or names of clothing or materials that contain silver fibers. Thus, if the MR Operator perceives there to be a risk that clothing contains silver fibers, participants will be asked to change into scrubs provided by the BRIDGE Center.

Participants should also be advised not to wear underwire bras containing metal for their scan.

If a study protocol requires that participants change into scrubs or other clothing that is not their own, those scrubs or clothing must be provided by the researchers. The BRIDGE Center keeps a small number of scrubs on hand for unexpected situations where it is necessary for a participant to change out of their street clothes. However, these are limited and researchers should not plan on using them regularly.

3.13 Accurate Participant Weight

- ⇒ **Weight accurate to within approximately five pounds should be entered into the MRI console for any person scanned.**

The scanners require that the participant's weight be entered before scanning. Accurate information must be provided to ensure that FDA limits for energy deposition are not exceeded. Weights should be correct to within five pounds. Incorrect information should **never** be entered in an effort to get the scanner to conduct a study that it otherwise would not perform because FDA limits would be exceeded.

SECTION 4: SAFETY STANDARD OPERATING PROCEDURES

Wean Hall Verio Safety Procedures

IMPORTANT CMU SAFETY CONTACTS:

CMU police (for Police, EMT, Fire): 412-268-2323 (8-2323 from a CMU phone)
The CMU Police dispatcher is the fastest way to obtain help from Police, EMT/Ambulance, and Fire. The CMU Police will dispatch all first responders. 911 can also be called, but CMU Police dispatch will provide a faster response time.

Environmental Health and Safety 412-28-8182 (8-8182 from a CMU phone)
Facilities Management: 412-268-2910 (8-2910 from a CMU phone)
Siemens Service: 1-800-888-7436

4.1 Safety Responsibility and Authority

- ⇒ **The MR Operator (usually the MR Technologist) is responsible for the screening and safety oversight of individuals in the BRIDGE Center.**
- ⇒ **In an emergency situation, other researchers, participants, and visitors should follow the instructions and assist the MR Operator.**

During times when they are the designated MR Operator, this is the person responsible for safety oversight in the BRIDGE Center. This means they are responsible for screening individuals before entering Zone 3 or Zone 4. The MR Operator may also at any time end a study, evacuate participants from Zone 4 and/or Zone 3, and take other actions they deem necessary if they perceive a safety risk. Researchers and participants should follow the MR Operator's instructions, and assist when requested in an emergency situation. While the MR Operator has safety oversight, researchers should voice any safety concerns they have to the MR Operator. This might include pointing out a missed or forgotten safety procedure, or a safety concern that the MR Operator might not have seen. Researchers should always feel they can raise a safety concern with the MR Operator. While safety oversight is the responsibility of the MR Operator, safety is a team effort and clear communication and safety procedures should always be practiced by all researchers in the BRIDGE Center.

4.2 MRI Quench – Emergency Magnet Run-Down

A magnet quench quickly dissipates the MRI's magnetic field and may be initiated by pressing one of the two Magnet Stop buttons. A quench should **only** be initiated by authorized personnel in the

event of a **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 MRI scanner. In non-life threatening situations, such as a piece of equipment being pinned against the magnet, no one should initiate a quench. In the event of a spontaneous ‘quench’ of the MRI system, follow procedure starting with Evacuation of all personnel and visitors.

The Right red “Stop” button under the plastic cover is the MR Quench button. This will trigger an alarm and initiate the quench. A quench may take 2-3 minutes to bring the field down, and there may still be a magnetic field present, so no metal objects should be taken in the room.

1. Quench **ONLY** if there is a personal or patient injury or injury risk:
 - A subject is “pinned” within or against magnet
 - A fire within gantry that cannot be extinguished.

2. A Quench is **NOT necessary**:
 - For an isolated projectile in magnet, without patient risk; the service engineer should be called.
 - In an emergency event (i.e. ER code, fire), if the patient can be removed safely.

- If a metallic object is attached to the magnet and a quench is not initiated:
 - Consider not using the patient bed controls!
 - Don’t risk moving the magnetic item!
 - If possible, recover the participant from the magnet bore leaving the attached item in place.



Procedures for Quench

- 1) Remain calm, and assess the situation.

- a) If warranted, push 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.
 - i) The decision to quench the magnet should be made by the MR Operator (Technologist) ONLY unless the MR Operator is incapacitated, themselves in danger of great physical injury, or for some other reason unable or unavailable to assess the situation and make a quench decision.
 - b) If a spontaneous quench occurs, inform the participant in the bore to stay calm, and to remain on the table. Follow the procedures below.
 - c) If a spontaneous quench occurs due to fire, follow the MRI fire procedures.
- 2) Notify nearby colleagues/staff of the emergency.
 - a) If available, other MR staff can initiate notification of appropriate emergency personnel.
Call 412-268-2323 (8-2323 from a CMU phone).
 - 3) Keep the Magnet Room (Zone 4) door propped open in case of a sudden cryogen gas release into the room.
 - 4) Proceed to vacate participant from the MRI bore:
 - a) Move table out of magnet automatically (if power is still on) or manually with table release (if power is out).
 - b) Assist participant in getting out of the Magnet Room as quickly as possible. If the participant is immobile or unconscious, move the participant from the MRI table to an MR compatible stretcher and then out of the Magnet Room.
 - c) For individuals pinned or trapped by a ferrous object, a quench will last approximately 1-3 minutes, at which time the ferromagnetic object may become dislodged. Proceed to vacate the participant after this time.
 - d) Transport participant to a safe area, which will be determined by the extent of the quench event, and the nature of participant injury (if any).
 - 5) Notify appropriate emergency personnel, if you have not already done so.
 - a) Determine who needs to be notified (i.e. police, fire, ER, etc)
(a) Call 412-268-2323 (8-2323 from a CMU phone).
 - 6) Despite a quench event, no ferrous material should be allowed in the Magnet Room (Zone 4) until zero magnetic field is confirmed.
 - a) If available, other BRIDGE Center staff members or researchers should remain near the entrance of the Magnet Room to prevent premature entry of emergency personnel.
 - 7) If there is a ferrous object it should not be removed from the magnet or Magnet Room until the patient is safely removed from the Magnet Room and the Scientific Operations Director or Co-Director is notified, unless the patient is trapped by the object.

4.3 Emergency Power Off

⇒ **The Emergency Power Off button stops electrical power to all parts of the MRI. However, the magnet will still be on!**

In addition to the two quench buttons, there are three Emergency Power Off Buttons:

1. In the Control Room to the left of the quench button.
2. In the Magnet Room under the quench button.
3. In the Equipment Room.

The purpose of the Emergency Power Off button is to:

1. Prevent electrical shock if there is water or coolant near equipment that may be electrified.
2. Help prevent or reduce fire due to electrical short or equipment failure.

Use Emergency Power Off For:

1. An electrical or other fire in the magnet room, control room, or equipment room.
2. Flooding of the center, liquid coolant leak, or sprinkler activation.
3. Catastrophic equipment failure or loud noises emanating from the magnet room.



4.4 Medical Emergency or Cardiac Arrest

- ⇒ **Never attempt resuscitation or medical treatment within the Magnet Room (Zone 4).**
- The participant must be moved from Zone 4 to Zone 3 or Zone 2.
 - Maintain access restrictions to Zones 3 and 4 during resuscitation or emergency situation.

Procedures for Medical Emergency

General Procedures

1. Stop scan immediately
2. Remove participant from magnet bore.
 - Use auto table retract, or manual table release (for power failure).
 - Assist participant in exiting the Magnet Room.
 - If participant is unconscious or unable to move, use MRI safe gurney to transport subject outside the Magnet Room according to procedure below.
3. Ancillary personnel (the second person) should:

- a. Call 412-268-2323 (8-2323 from a CMU phone).
 - b. Prevent outside emergency team from entering Magnet Room (lock room if able).
4. If patient is unconscious or experiencing cardiac symptoms, on person should retrieve an AED (Automated Electronic Defibrillator).
5. Direct Emergency team quickly once they arrive.
6. Provide any assistance necessary.

If participant is unconscious or cannot move

1. Retrieve MR compatible stretcher from the BRIDGE Center Conference Room.
2. Use MR compatible stretcher to remove the participant from the Magnet Room.
3. Enlist the help of other MR trained personnel if necessary to move participant.
4. Do not allow EMS to bring a stretcher that is not MRI safe into the magnet room.
5. Once the participant is outside the magnet room they may be transferred to an EMS stretcher and transported to a different room to be cared for.

If someone experiences cardiac arrest:

1. Call CMU Police at 412-268-2323 (8-2323 from a CMU phone).
2. If in the magnet room immediately remove them.
3. If you know CPR, start chest compressions.
 - a. Send second person to retrieve AED.
4. If you do not know CPR, retrieve an AED. **DO NOT bring an AED into the magnet room.**
 - a. Nearest AEDs are on 4th floor of Wean near the Osher Lifelong Learning Center (4707/4708 Hallway) and in the 5th floor lobby.
5. Open the AED case and follow the step-by-step audio instructions.
6. Stay with the person until help arrives.

If someone experiences an MR burn injury:

1. Request emergency assistance by calling 412-268-2323 (8-2323 from a CMU phone).
2. Immediately remove the participant from the scanner.
3. Apply a cold towel to the burned area until EMS arrives.

Table movement injury:

A table stop button is located on the top of the intercom in the control room and on the magnet itself.

- **This should be activated only in case of injury due to table movement.**
- This will stop motorized table movement.
- If a medical emergency or serious injury has resulted, follow general procedure.

4.5 Panicked Participant

1. Remove participant from magnet and evacuate to waiting room.
2. Remain calm, speak softly, and reassure the participant that everything is alright and that their reaction is understandable and is not uncommon.

3. Be empathetic.
4. Enlist help of investigators, family, etc.
5. Call 412-268-2323 (8-2323 from a CMU phone) for help if needed.

4.6 Threatening or Dangerous Participant

1. If you are the second person in addition to the MR Operator not dealing directly with the participant Call 412-268-2323 (8-2323 from a CMU phone) immediately and request CMU Police assistance.
2. Speak softly and refrain from having a judgmental attitude.
3. Try to remain neutral, although it may be difficult with an irrational participant.
4. Put some distance between yourself and the participant, and do not make intense eye contact.
5. Try to demonstrate control of the situation without becoming demanding or authoritative.
6. Seek to smooth the situation over rather than bully the patient into better behavior.
7. Evacuate the center if necessary and **Call 412-268-2323 (8-2323 from a CMU phone) immediately.**

4.7 Fire or Explosion

1. Remain Calm.
2. Activate the fire alarm! Nearest alarm pull handle is off the main corridor across from computer science receiving.
3. Retrieve the participant from the magnet.
4. Close and lock the Magnet Room door.
5. Evacuate the building.
6. Remain near the building for fire response team.
7. If you encounter smoke while evacuating, get close to the floor where the air is coolest and smoke free.
8. Feel the door with the back of your hand before you open it. If the door is cool, open it slowly. If the door is hot, or if you detect smoke on the other side, do not open it, unless a person on the other side is seeking assistance. Seek another way out.
9. If you cannot get out shelter in a safe place, call CMU Police 412-268-2323, call or text a friend or yell for help. Attempt to make yourself visible to responding authorities.

Only if it is a small fire and safe to attempt, use one of the MR-safe (Blue and White) Fire Extinguishers located in Zone 3, the Waiting Room, and the Equipment Room to extinguish the fire. Then call CMU Police at 412-268-2323 (8-2323 from a CMU phone).

Fire Alarm in the Building

1. Remain Calm.
2. Immediately remove participant from scanner
3. Close and lock the scanner room door.
4. Evacuate the building.



4.8 Power Outage

1. Remain Calm.
2. If emergency lighting does not activate, shine a flashlight through the control room window. **Do not take a flashlight into the Magnet Room!**
3. Use the manual table release to pull the table out and remove participant from scanner.
4. Close and lock the magnet room door.
5. Notify FMS of the outage if necessary and evacuate the Center.

4.9 Phantom Fluid or Glycol Spills

1. Do not use damaged/leaking phantoms!
2. Avoid skin contact with fluid leaking from any phantom.
3. Put on disposable protective gloves and goggles/face mask if available.
4. Absorb fluid with absorbent material (towels, sand, sawdust).
5. Place absorbent material and phantom a plastic bucket.
6. Contact Environmental Health and Safety (412-268-8182) for disposal and additional cleanup advice.
7. Change contaminated clothing
8. Wash hands thoroughly with soap and water.
9. Contact Siemens Service with additional questions.

First Aid for contact with phantom fluid or glycol.

Skin Contamination

- Immediately remove contaminated clothing.
- Immediately wash skin with soap and water.

- Immediately consult a physician.

Eye contamination

- Immediately consult an ophthalmologist at UPMC-Presbyterian.

Ingestion

- Drink plenty of water and induce vomiting
- Immediately consult a physician.

Inhalation

- Move yourself or participant to fresh air.
- Immediately consult a physician.

4.10 Building Lockdown

1. Remain Calm.
2. If time, lock main door and turn off waiting room lights.
3. Close Control Room door (it will lock automatically).
4. Remove participant from scanner.
5. Close and lock magnet room door.
6. Shelter in place in Control Room until notified that it is safe to leave the building.

4.11 Active Shooter

If shooter is not inside the BRIDGE Center shelter in place:

1. Remain Calm.
2. If time, lock main door and turn off waiting room lights.
3. Close Control Room door (it will lock automatically) and turn off lights.
4. Remove participant from scanner.
5. Close and lock magnet room door.
6. Call CMU Police at 412-268-2323.
7. Shelter in place in Control Room until notified that it is safe to leave the building.

If shooter is encountered directly:

Run:

1. Immediately run away from the gunman or from sounds of gunfire.
2. Get to a safe place and call CMU Police at 412-268-2323.

Hide: If you can't run...

1. Close, lock and block the door.

2. Turn off lights and silence phones.
3. Hide under a desk, in a closet or behind a wall or furniture.

Fight: If you can't run or hide...

1. Find anything that can be used as a weapon.
2. Attack the shooter when possible.

4.12 Theft or Center Break-In

- Contact Scientific Operations Director or Co-Director and provide a detailed report.

4.13 Information for Emergency Personnel

- Identify the location of the Center: Wean Hall Room 3604, Carnegie Mellon University.
- If possible have a second researcher provide directions or meet the emergency personnel if necessary.
- Inform personnel that the magnet is always on, and even in the event of a quench may still have a magnetic field.
- Screen them for metal in the body as you would anyone else who enters the Magnet Room.
- Ensure that they understand that no metal may be brought into the magnet room.

4.14 Accidents, Injuries, and Incidents

Any accidents causing injury to an individual or research participant must be reported to the BRIDGE Center Safety Committee by the researcher conducting the study. If an accident or injury occurs that is not related to an MRI study, then the MR Operator or individual on site who is responsible should report to the Safety Committee. Besides reporting to the Safety Committee, the accident, injury or incident may need to be reported to Carnegie Mellon University and the Institutional Review Board(s).

SECTION 5: SAFETY INFORMATION

5.1 Static Magnetic Field

The Magnet is always ON!

⇒ *It is important to remember when working around a superconducting magnet that the magnetic field is always on. Under normal working conditions the field is never turned off. Therefore, it is important to be aware of safety issues regarding ferrous projectiles and volunteers who may have contraindicated devices implanted in their bodies.*

Background

The most common breaches of MRI safety occur due to an object being attracted to the 3 Tesla Static Magnetic Field. An individual may be struck, injured or trapped against the magnet by the object. Equipment may be damaged by slamming into the magnet or being struck by another object that is accelerating rapidly due to the strong attraction of the magnetic field. The Static Magnetic Field is the main magnetic field of the scanner generated by the superconducting electromagnet that is always present once the magnet is ramped up to the designated field strength. The field increases non-linearly as an individual approaches the bore (opening) of the magnet and the field map depends on the particular magnet configuration. The static magnetic field is described in units of Tesla (T) with 1 T equal to 10,000 gauss. The magnetic field strength of the Siemens Verio in Wean Hall is 3 Tesla (3T). The distance from the magnet that is safe for the general public and to use all objects and devices is denoted as the 5 gauss line, and is 3-dimensional around the magnet. The area immediately within the 3-5 gauss line or toward the magnet is called the fringe field. The researcher must be aware of which objects and devices are safe to move into the static magnetic field.

Projectile Effect

Items that are ferromagnetic have the potential of becoming projectiles when brought into the magnetic field. Depending on the mass and magnetic properties of the object, serious injury could result as the object is attracted by the static field into the bore of the magnet. It must be noted that objects accelerate extremely rapidly when captured by the magnetic field and the path of travel is unpredictable once within the strong field. Projectiles have the potential of causing serious injury including death, to anyone who may be in the path of the object as it accelerates toward the magnet. Projectiles may cause an individual to be pinned to the magnet. Equipment may be irreparably damaged by becoming a projectile or by being struck by one. Reports indicate that projectiles continue to be a persistent safety concern for all MRI centers. Projectiles have caused a multitude of serious personal injuries within the United States including death.

Because the magnet is actively shielded, the initial magnetic field you experience on entering the magnet room is fairly low; probably too low for you to feel on your belt buckle or on the

screwdriver you've absentmindedly carried in with you. However, the magnetic field increases VERY rapidly as you approach the magnet. You may not feel the magnetic field's effect on a magnetic item until you are near the patient bed, by which point the item will probably be pulled from your hands! Magnetic items are therefore prohibited in the Magnet Room (Zone 4).

Any iron-containing object, including all types of steel (even 'surgical-grade' stainless steel), should be assumed to be magnetic. Certain other metals, like nickel, also exhibit "ferromagnetism." Most batteries contain magnetic components, for example.

Magnetic objects commonly found in the lab, or on people entering the lab, include: flashlights, cellphones, work tools, scissors, ring binders, sunglasses, paper clips, calculators, keys, chairs, brooms, shoes (their rivets), belt buckles, hair clips, and even "aluminum" ladders which use steel rivets, and wooden stools which use steel screws! In fact, once you start looking for magnetic parts you'll quickly find that most common items have some amount of ferromagnetic metal in them, unless they are specifically designed to be MR safe.

Magnetic objects on casters (wheels) – such as chairs – are particularly risky objects near high magnetic fields. Don't take chairs into the Magnet Room!

When a magnetic object encounters a magnetic field it will experience two types of motion. First, it will experience a torque and try to orient itself such that its longest magnetic axis is parallel to the field direction. Second, if it experiences a magnetic field *gradient* the object will tend to move towards the higher field region, *i.e.* it will move towards the center of the magnet. It will continue moving - and accelerating - until it reaches a homogeneous field region, *i.e.* the center of the magnet.

The speed attained by an item on its journey to the magnet center depends on many factors, including the object's mass and shape. But speeds can easily exceed 70 mph almost instantaneously. In fact, the speed can be so high that a magnetic object may have sufficient momentum to pass through the magnet center and continue towards the magnet rear, even exiting the rear of the magnet briefly before being sucked back in! Most objects oscillate between the poles (ends) of the magnet until friction with the air and frequent impacts with the inner magnet surface degrade the momentum.

People have been killed after being struck or crushed by a magnetic object attracted onto an MRI magnet. Many other people have been very seriously injured. Objects that are too large to enter the magnet bore will come to rest on the face of the magnet where, although stationary, they continue to exert **massive** forces. The object will likely crush anything or anyone with the misfortune to be between it and the magnet. Forces in excess of 2,000 lbs (or one ton!) were measured on a standard office chair stuck on the front of a 4 T magnet. If you were the subject on the patient bed at the time, this would essentially be equivalent to having a car fall on you. Serious injury or death is all but assured.

You should also be aware of the effects of the magnetic field on other equipment. Most electronic devices respond poorly to high magnetic fields and will malfunction - often permanently - in a field

greater than about 20 G. For example, micro-switches and relays can "stick" open or closed in such magnetic fields. The failed/failing device may present new hazards as a consequence. Analog watches will stop and possibly break in a high magnetic field. Magnetic "swipe" strips found on credit cards, phone cards, ID cards will be wiped above about 50 Gauss. (That's not particularly dangerous, but it is annoying and could well be expensive.) Leave your laptop, wallet, watch, keys, spare change, cellphone and sunglasses in the appropriate operator screening area.

Torsion and Translation Forces

Ferromagnetic objects or devices, including those within the human body will be attracted to the magnet. Ferromagnetic objects or devices, including those within the human body, will attempt to align parallel with the main magnetic field. This includes metal fragments within the eyes, ferromagnetic brain aneurysm clips and other implanted medical devices.

Magneto Hydrodynamic Effects

For some patients, rapid head movement while in the magnetic field may cause dizziness, vertigo, or a metallic taste in their mouth. It is believed that some of these effects, particularly vertigo, nausea, and phosphenes (visual sensations arising from mechanical or electrical stimulation of the eye), may be related to magneto hydrodynamic phenomena. These effects are known to become more evident with increase in static magnetic field strength. Magneto hydrodynamic is defined as: *of or relating to phenomena arising from the motion of electrically conducting fluids in the presence of electric and magnetic fields.* These effects are likely only to occur during quick movements of the head within the magnetic field. Moving the research participant slowly in and out of the scanner and restricting head movement should eliminate these sensations. It is recommended that individuals and participants who may be experiencing magneto hydrodynamic phenomena also restrict side to side head movement and move more slowly near the scanner.

Lenz's Forces

Faraday's law states that a moving or changing magnetic field will induce a voltage in a perpendicularly oriented electrical conductor. Lenz's law builds on this rule and states that the induced voltage will be such that it will secondarily generate its own magnetic field whose orientation and magnitude will oppose those of the initial time-varying magnetic field that created it. Thus an object may be non-ferromagnetic and still be influenced by the magnetic field of the scanner magnet. This may cause confusion if the magnetic tug is felt in a designated MR safe device erroneously leading to the conclusion that the object is not safe after all. Moving such items and objects very slowly in the magnetic field will reduce the effect of the Lenz's forces.

5.2 Radiofrequency and Thermal Heating

Radiofrequency and SAR

When the scanner is acquiring images, the radiofrequency oscillating (123 MHz) magnetic field generated by the transmission RF coil causes a low amount of energy to be deposited as heat into a subject lying in the magnet. On the Siemens Verio 3T, the transmission RF field is produced by a body-sized coil which runs the entire length of the magnet. (The coil can't be seen from the

outside, it is hidden behind the bore liner of the magnet.) During a scan an estimate of heating is done based on the subject's weight (as given in the patient registration step). Assuming the person has normal physiology, this *specific absorption rate* (SAR) monitor will assure that the heating effect is kept within safe limits, which are regulated by the FDA. The heating effect of MRI with the SARs used in accord with these guidelines is extraordinarily unlikely to cause any acute effects in healthy human subjects.

Focal Heating

Note, however, that the SAR monitor assumes there is no *focal* heating, as can happen with certain tattoos or pierced jewelry, for instance. Looped conductors within the bore must be avoided at all cost. *Metal jewelry is highly electrically conductive and can provide a convenient 'sink' for the RF power.* So, even if a scan can be run safely according to the RF monitoring software, it does not mean there is no burn risk to the subject!

5.3 Gradient Fields and Peripheral Nerve Stimulation

MRI uses pulsed linear field gradients (commonly referred to as simply "the gradients") to encode spatial information into the RF signals being excited and detected. All imaging sequences use pulsed gradients. Fast imaging sequences, such as echo planar imaging (EPI) as used for functional MRI, use gradients that are pulsed very quickly. Furthermore, this gradient pulse doesn't occur in isolation, but with several hundred similar pulses over the course of a second or so. The net effect is that the switching field gradients set up induced electrical currents inside the subject's body. Fortunately, the threshold necessary to generate such effects as peripheral nerve stimulation (PNS) is fairly high relative to the size of the electrical currents being induced, and to date most reports have been limited to mild discomfort, tingling, muscle twitches and, very rarely, visual flashes (magneto-phosphenes being triggered in the eye).

As with RF heating, the scanner software monitors the gradient switching and makes estimates of the likely limit that might cause PNS. Based on the subject's weight, approximate body dimensions are estimated and used to determine whether the scan is likely to trigger stimulation or not. If the estimate is above a threshold the scan will not run. Note, however, that this is all done by estimation; the only measurement being done is of the gradients themselves. The scanner can only estimate the subject's tissue conductivity and geometry. A subject might still experience localized peripheral nerve twitching without warning.

To minimize the possibility of PNS you should instruct your subjects to lay in the magnet with their hands by their sides and with their feet uncrossed. This minimizes large current loops around the body. If the subject experiences discomfort during the scan then he should alert you via the squeeze-ball and you can abort. However, it is generally not a good idea to describe in detail all the ways the subject might feel discomfort because there have been many instances where the subject has misinterpreted the vibration of the patient bed for muscle twitching. That said, do make sure the subject is confident you will stop the scan if he or she feels at all uneasy or uncomfortable! It is also safe to proceed with a scan in which the subject feels twitching, if the

subject is happy to continue and if you are confident the subject won't be unduly distracted from an fMRI task.

5.4 Acoustic Noise

Gradients and Acoustic Noise

The second effect of the pulsed gradients is more easily recognized: acoustic noise from the strong Lorentz forces occurring inside the gradient coil. Whenever a current is passed through a wire that is located in a magnetic field, the wire will try to move in a perpendicular direction to the current and magnetic flux directions. (You may recall Fleming's Left Hand Rule from high school physics.) The higher the current and the larger the magnetic field, the larger the motion. So why doesn't the gradient coil simply fly out of the magnet when it is pulsed? The answer is that it would, were the forces not balanced so that the force trying to eject the coil from the front equals that acting in reverse.

What's more, the wires that comprise each gradient coil's windings are also experiencing their own localized attempts to move. The reason an individual copper wire doesn't fly off the coil is simply because the whole coil is "potted" in a tough epoxy resin. The sum total of all these attempts at motion are the familiar, and extremely loud, "banging" or "pinging" sounds that emanate from the magnet during a scan. EPI can generate noise as loud as 120 dB, necessitating certain operating procedures to prevent damage to hearing in subjects and operators alike.

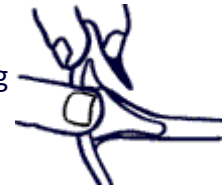
Ear Protection

It is essential that all subjects be properly fitted with earplugs prior to entering the magnet. Anyone who will accompany the subject in the magnet room during the scan must also be fitted with earplugs. To fit earplugs, squeeze and roll the earplugs along their full length (not just the tip), pull the earlobe slightly backwards and insert the plug almost all the way to the ear canal. Hold in place until the plug inflates over about thirty seconds; the user will hear the gradual muffling of the external noise as this is happening. Only the very end of the plug should be visible outside the ear canal. The more it is in, the better the noise blocking.

If possible, fit your subjects with headphones as well as earplugs. These allow easy communication with your subject as well as additional scanner noise protection. If it is not possible to fit headphones inside the RF coil (*e.g.* because you're using the 32-channel head coil), consider placing foam padding over the subject's ears as a secondary noise attenuating device. To minimize the sound reaching the operating room, and to maintain the integrity of the RF shielded room that prevents external interference with the MR measurement, it is imperative that the magnet room door be kept closed during all MR scans.

How to properly instruct subjects to insert ear protection:

1. Hold the ear plug between your thumb and forefinger. Roll and compress the entire ear plug to a small, crease-free cylinder. While still rolling, use your other hand to reach over your head and pull up and back on your outer ear. This straightens the ear canal, making way for a snug fit.
2. Insert the ear plug and hold for 20 to 30 seconds. This allows the ear plug to expand and fill your ear canal.
3. Test the fit. In a noisy environment, and with earplugs inserted, cup both hands over your ears and release. You should not notice a significant difference in the noise level. If the noise seems to lessen when your hands are cupped over your ears, your ear plugs are probably not fitted properly. Remove and refit following instructions
4. Always remove ear plugs slowly, twisting them to break the seal. If you remove them too quickly, you could damage your ear drum.



5.5 Cryogen Risk During Quench

During a planned or accidental shutdown of the magnetic field, quench, the liquid Helium in the magnet turns into gas and may escape into the scan room displacing the oxygen in the room leading to asphyxia. Quenching is the process whereby there is a sudden loss of absolute zero of temperature in the magnet coils, so that they cease to be super conducting and become resistive, thus eliminating the magnetic field. This results in helium escaping from the cryogen bath extremely rapidly. It may happen accidentally or can be manually instigated in the case of an emergency. Quenching may cause severe and irreparable damage to the super conducting coils, and so a manual quench should only be performed in extreme cases when the technologist and service engineer are involved in the decision to quench. All systems should have helium-venting equipment, which removes the helium to the outside environment in the event of a quench. However, if this fails, helium will vent into the room and replace the oxygen. For this reason all scan rooms should contain an oxygen monitor that sounds an alarm if the oxygen falls below a certain level. Under these circumstances immediate evacuation of the patient and personnel is necessary. It is noted that if the scan room door is closed when a quench occurs and helium escapes into the scan room, the depletion of oxygen causes a critical increase in pressure in the room compared with the control area. This produces high pressure in the scan room, which may prevent opening of the door. If this should happen, the glass partition between the scan and control rooms should be broken to release the pressure. The scan room door can then be opened as usual and the patient evacuated. In such a case the patient should be immediately evacuated and evaluated for asphyxia, hypothermia and ruptured eardrums.

APPENDICES

- A. Rates**
- B. Project Registration Form**
- C. MRI Screening Form**
- D. Pre-Screening Sample Questions**

Appendix A – Fees

In order to meet the operations goals for the new center and maintain a balanced budget we will be changing the hourly rates over the next few years. A summary of the rates across the next five years is below.

	FY19	FY20	FY21	FY22	FY23
Direct costs	\$460	\$495	\$530	\$540	\$550
Total costs	\$580	\$624	\$668	\$680	\$693

These rates have been agreed to by a steering committee made up of six center users from both campuses. This structure is designed to meet our budget goals over the next five years, with a steady 2% increase per year beginning in fiscal year (FY) 2022. Importantly, both Pitt & CMU have agreed to a partial indirects model, whereby only a 26% Administration charge will be applied to each billed hour as opposed to the full indirect rate. Thus the smaller difference between direct and total charges. For comparison, the previous total charges for SIBR hours was \$500/hour when full indirects are applied.

The new rates for FY2019 take will effect as of August 1st, 2018 and will be the same for hours collected on **both** the (new) Prisma and (current) Verio systems.

PROJECT REGISTRATION

CMU-Pitt BRIDGE Center

Project Name:				
Project Short Name:				
Principal Investigator Name:				
Lab/Research Group Name:				
Department:		Institution:	<input type="checkbox"/> CMU <input type="checkbox"/> Pitt <input type="checkbox"/> Other	
Email:		Office Location:		
Office Phone:		Mobile (emergency) Phone:		

Project Personnel

Primary Project Contact:		Email:	
Billing Contact:		Email:	

Project Team Members (use Additional Project Personnel sheet if needed)

Name	Position	Role	Email	Approved

BRIDGE Center Use

Project Review

BRIDGE Center Project ID:				
Date Submitted:		Review Type:	<input type="checkbox"/> Expedited Review <input type="checkbox"/> Full Review	
Review Approval:		Date:		

CMU IRB Review

IRB #:		Date Approved:		Expiration:	
Documents Received:	<input type="checkbox"/> Approval Letter <input type="checkbox"/> Full Protocol Text <input type="checkbox"/> Consent Form				

External User Agreement (EUA)

EUA #:		Date Approved:		Expiration:	
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FINAL APPROVAL:		Date:	
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Additional Project Personnel


<i>Project Team Members</i>				
Name	Position	Role	Email	Approved

Additional Notes

CMU-Pitt BRIDGE* Center - MRI Safety Screening

PI _____  Position/Tilt _____

Date (mm/dd/yyyy)	/ /	Time in:	Time out:
Name (last, first)			Gender F M
Birthdate (mm/dd/yyyy)	/ /	Tel	Weight #
Email			



WARNING: The magnet of the MR system has a very **strong magnetic field** that is dangerous to a person entering the magnet room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. **The magnet is always on.**

Metallic and electrical objects in your body	Aneurism clip?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Have you had a prior surgery or operation?	<input type="checkbox"/> No <input type="checkbox"/> Yes	Neuro stimulator? <input type="checkbox"/> No <input type="checkbox"/> Yes
Have you ever been injured by a metallic object?	<input type="checkbox"/> No <input type="checkbox"/> Yes	Cardiac pacemaker? <input type="checkbox"/> No <input type="checkbox"/> Yes
Electronic, mechanical or magnetic implant?	<input type="checkbox"/> No <input type="checkbox"/> Yes	Implanted hearing aid? <input type="checkbox"/> No <input type="checkbox"/> Yes
Intravascular stents, filters, or shunts?	<input type="checkbox"/> No <input type="checkbox"/> Yes	Denture work, braces? <input type="checkbox"/> No <input type="checkbox"/> Yes

Pre-existing medical conditions: Do you have a medical history of developing **seizures, ear infections/ear problems** or currently suffering from **cold/flu symptoms, claustrophobic reactions**, or greater than normal potential for **anxiety** and/or cardiac arrest? Aware of any **brain anomalies**?

No Yes

Metallic objects: Please **Remove all metallic objects** before entering the magnet room including hearing aids, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, hair bands, belts, metal underwire bras. *Do not wear anti-microbial athletic clothing containing silver or gold threading.*

Do you have any metallic or ferromagnetic object left on you?	<input type="checkbox"/> No <input type="checkbox"/> Yes
IUD? (3T compatible IUDs are: Mirena, Lippey Loop, and Liletta)	<input type="checkbox"/> No <input type="checkbox"/> Yes
Are you pregnant?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Signature of Subject/Guardian

Confirmation by MRI Operator

Appendix D – Pre-Screening Sample Questions

MRI Pre-Screening

The following is an example set of questions for pre-screening participants to scan at the BRIDGE Center. The approach to screening for safety critical questions such as implants or metal in the body is to ask the question multiple times in different forms. This approach decreases the risk that a critical contraindication for MRI might be missed.

Questions can be divided into four categories:

1. **Demographic Information:** Questions including name, birthdate, weight, and contact information. Some of this information is for contact purposes, other information is related to safety (weight), and other is related to IRB protocol compliance (participant is within age range).
2. **MRI Safety Screening:** Questions for ensuring that the participant has no contraindications for the MR environment and that they are safe to scan. *Pre-screening should definitely include these questions.*
3. **Data Quality Screening:** These questions are regarding things that do not pose a safety risk for being scanned in an MRI, but could indicate poor data quality or other problems from a research perspective. *These questions are highly recommended to be included.*
4. **Research Exclusion Questions:** These questions are specific to a particular experiment and are given as examples of things that might exclude someone from participation. *These questions are optional but recommended.*

Below is a set of example questions along with the reasoning for the question provided in italics. The pre-screening questions can be conducted via in person interview, on paper, phone interview, or secure online survey (e.g. Qualtrics). The questions are presented in no particular order. The pre-screening questionnaire should be IRB approved and might require consent or assent before questions are asked depending on IRB requirements.

Demographic Information

- Name, Email, Phone Number?

Contact information for the participant.

- Male or Female?

To confirm if questions specific to female participants have been completed.

- Age?

The age of the participant must be within the IRB approved age range for the study.

- Weight & Height?

The correct weight must be entered into the MRI console to properly calculate SAR restrictions. In addition, this information can be used to verify if the participant can comfortably fit in the Verio MRI.

MRI Safety Screening

- Have you had a prior surgery or operation? If yes, please describe in next question.

The first of a number of questions to confirm if the participant has any implants or items in their body that are not MRI compatible.

- Do you have non-removable electronic, mechanical or magnetic implants anywhere in your body (metal screws, etc.)? If yes, please describe the metal implants below.

Another question to confirm the participant does not have a pacemaker, stent, or other object not compatible with MRI in their body.

- Have you ever been injured by a metallic object or foreign body (e.g. BB, bullet, shrapnel, etc.)? If yes, please describe the injury below.

Another question to confirm the participant does not have ferrous metal in their body.

- Do you have any intravascular stents, filters, aneurism clips, or shunts?

This question is technically covered by the above questions, but is re-asking the question as a confirmation that the participant does not have the most dangerous MRI contraindications.

- Do you have a cardiac pacemaker?

This question is technically covered by the above questions, but is re-asking the question as a confirmation that the participant does not have the most dangerous MRI contraindications.

- Do you have a cochlear implant?

This question is technically covered by the above questions, but is re-asking the question as a confirmation that the participant does not have the most dangerous MRI contraindications.

- Do you have any non-removable body piercings?

All piercings (even non-ferrous) must be removed before scanning due to risk of the metal heating and causing burns.

- Do you have an IUD? If so, indicate which one.
 - No, I do not have an IUD.
 - Mirena
 - Paragard (copper)
 - Skyla
 - Liletta
 - Kyleena
 - Lippy Loop
 - I have an IUD but I don't recall/don't know which one.

Only three IUDs are 3T MRI compatible without restriction: Mirena, Liletta, Lippy Loop. All other IUDs FDA approved in the United States have a metal component (copper for Paragard, silver rings in Skyla and Kyleena), and are thus not 3T MR Safe and will not be scanned at the BRIDGE Center.

- Do you have any large tattoos?

Most tattoos are fine for MRI scanning. However, the MRI Technologist may ask for details about very large tattoos, tattoos on the head, and old tattoos. The ink in some tattoos (especially older) can contain iron and thus cause irritation.

- Have you ever done any welding, grinding, or cutting of metal in your lifetime? If so, please describe how much, whether or not you wore eye protection, and if you ever had an injury while working with metal.

The primary concern with this question is if the participant has had an injury to the eye with metal. A metal shard in the eye could potentially move as the participant enters the MRI and cause eye or nerve damage.

- Females: are you pregnant, or suspicious you may be pregnant?

As per the BRIDGE Center pregnancy policy, pregnant women are not to be scanned unless the study meets the specific exception criteria.

- Do you have a medical history of developing seizures?

There is a possibility that the RF pulsing and changing gradients might induce seizures. Thus individuals with a history of seizures should discuss their condition with the MRI Technologist

- Do you have a history of claustrophobia or discomfort with confined spaces?

Individuals known to be claustrophobic should not be scanned.

- Are you able to tolerate loud noises for sustained periods of time?

Even with earplugs, the MRI scanner is loud and individuals with sensitive hearing should not be scanned.

- Have you experienced any problem related to a previous MRI examination or MR procedure? If yes, please describe the problem in next question.

This question is a check for any unusual or unexpected problems that the participant might have experienced in a previous MRI scan.

- Do you currently have an ear infection or any ear pain?

It is possible that the loud noise of the MRI scanner and vibrations could aggravate an existing ear infection. An ear infection or ear congestion can also make it difficult to determine if earplugs are properly inserted. Therefore the BRIDGE Center does not scan participants with an active ear infection or ear pain.

Data Quality Screening

- Do you currently have braces?

Braces are safe in the MR environment, but they will cause large artifacts in MRI scans and make data essentially useless. Thus participants with braces should not be scanned.

- Do you have a permanent retainer?

- No
- Yes - top retainer
- Yes - bottom retainer

Permanent retainers are also MR safe but can cause data artifacts. Bottom retainers will cause dropout in the mouth region on MPRAGE anatomical scans but generally do not

interfere with fMRI data quality or MPRAGE quality in the actual brain. Top retainers however usually cause artifacts in the frontal lobe of anatomical and fMRI scans and are thus not recommended to scan.

- If you wear glasses, do you also have contact lenses available?

Contact lenses are typically easier for MRI scanning than glasses for those who do not have normal vision. However one risk of contact lenses is eyes drying out while in the scanner which can cause excessive blinking and discomfort.

- If you wear glasses, what is your prescription?

The BRIDGE Center has two sets of MRI compatible glasses. However there is a limited prescription range so it is best to know the prescription of your participant ahead of time. Knowing your participant's prescription also allows for a faster setup time since lenses do not have to be tried out.

- Are you able to hold still for over an hour?

It is usually a good idea to ask participants if they can hold still for a long period of time. Excessive motion will make the scan data unusable. If a participant knows they are fidgety they might not be suitable to participate in MRI.

- Do you currently have a cold, or allergies that result in sneezing or coughing?

Any sneezing or coughing during the MRI scan will cause excessive motion and most likely make the data unusable.

Research Exclusion Questions

Research exclusions questions are highly dependent on the study criteria. These criteria should be carefully considered and participants should be screened for anything that might exclude them before they are scheduled for an MRI study session.

Common criteria include:

- Handedness
- Color blindness
- Native language
- If the participant is taking psychoactive medication
- Etc.