RUBIC (Rutgers University Brain Imaging Center) Common Practices

The following minimal set of common practices applies to all human subjects research performed at RUBIC. To streamline processing, each individual protocol should include the statement 'This protocol follows the RUBIC Common Practices (date: 06/23/11).'

Additional exclusions or other procedures can simply be documented in a researcher's IRB application. Research proposals that wish to use only a subset of these common practices require approval by both the IRB and the RUBIC Executive Committee; these should be addressed in a separate section of the protocol entitled "Deviations from RUBIC Common Practices." The common practices outlined in this document apply only to adult, non-clinical populations. The recruitment of special populations (e.g., children, prisoners, clinical patients) will require a separate section of the protocol entitled "Child Participants and/or Participants Drawn from Nonstandard Populations" in which any additional risks, precautions, or methodology will be described.

RUBIC ADMINISTRATIVE STRUCTURE

Management of RUBIC is performed by the RUBIC Executive Committee consisting of the Director (S. Hanson, Psychology) and two associate directors (M. Delgado, Psychology and B. Krekelberg, Center for Molecular and Behavioral Neuroscience (CMBN)) is responsible for the day to day running and maintenance of the device and access to the center. Policy application, research development, and budget management will be determined by the RUBIC Executive Committee. An MRI tech or other knowledgeable individual will be available for consultation and advice when users are scanning.

USER AUTHORIZATION

Any user of RUBIC will be required to have a currently approved IRB protocol and the necessary funding to scan.

Training and certification of users will be performed under the direction of the RUBIC Executive Committee. A Principal Investigator (with an approved Rutgers IRB protocol) will be allowed to designate him/herself or senior personnel from his/her lab for training. The training procedure is outlined in the Training section of this document and in Appendix D.

Designated personnel at RUBIC will:

1. provide safety and other training related to the use of the MRI

2. confirm that each potential user of the RUBIC center has completed the training required at the appropriate access level before the scanning session begins

3. maintain administrative records associated with RUBIC, including training and safety records

HYGIENE

Linens used for a scanning session will be changed for each participant.

Animal scans at RUBIC require prior approval of the Rutgers Animal Care and Facilities Committee and the RUBIC Executive Committee. The PI is responsible for taking great care to avoid animal

bodily fluids or feces from coming into contact with the scanner or other RUBIC equipment. This will be accomplished by:

1. Animals will be kept at all times in containers that minimize the possibility of spills.

2. Absorbent pads and drapes will be placed below the animal to cover the scanner bed, bore, and other equipment.

3. Animal handlers will wear gloves while handling the animal and must remove these gloves before touching control panels, video equipment, telephones, doorknobs, elevator buttons, or other objects in shared spaces, including the control room.

4. Following CDC recommendations, immediately after the animal has left the facility all equipment that may have been in contact with the animal will be cleaned with diluted bleach (10%) solution. This applies in particular to the coils, any monitoring equipment, and the scanner bed and bore. Human subjects will not be allowed in the scan room until it has been cleaned. The PI is responsible for the appropriate disposal of all waste materials.

EXCLUSION CRITERIA

Participants are excluded from participation if they meet one or more of the following criteria:

- ferrous material implanted in or on the body, including flakes or filings, surgical pins or plates, electrical devices such as a pace maker, jewelry, or lead tattoos.

- pregnancy

- claustrophobia or anxiety in small enclosed spaces

SCREENING

All potential participants will be screened to determine whether they can safely enter the MRI environment. Screening is done in three stages:

Verbal screening:

When the potential participant is first contacted for scheduling, he/she will be asked if he/she has embedded medical devices, embedded metal, lead tattoos, anxiety in small spaces, or if she is pregnant. If the potential participant responds in the affirmative to any of these questions, he/she will be excluded as a participant.

Written screening:

When the participant arrives at RUBIC, and before scanning, the participant will complete an MR Screening Form (See Appendix A). The form will be filled out by the participant and reviewed by the researcher (Level 2 or Level 3 training). Any potential participant who is determined to be at risk based on his/her responses will be excluded as a participant.

Physical screening:

Following completion of the MR Screening Form, and before entering the scan room, the participant will be reminded to check his/her pockets for any cards with magnetic strips, or any metallic objects. Lockers will be available for personal effects. A ferromagnetic detection device (e.g., the Mednovus Safescan target scanner) will be used to determine if the participant has any ferromagnetic material on or in his/her person before being allowed to enter the scan room.

Pregnancy screening:

In addition to the verbal and written screening described above, female participants will be given the opportunity to take a pregnancy test (provided by RUBIC) prior to being scanned. Should the participant not wish to take a pregnancy test, she will be asked to sign a release form indicating that she refused the offer of a pregnancy test (See Appendix B).

COMMUNICATION WITH PARTICIPANT IN THE SCANNER

A two-way audio connection will be used to communicate with the participant while (s)he is in the scanner. In addition, the participant will be given a "panic" button which (s)he can press to indicate the desire to terminate the study immediately. The participant will also be monitored visually from the control console. The participant will be removed from the scanner immediately if (s)he so requests.

EQUIPMENT

All equipment used in the MRI room will be tested for MR safety and compatibility by the RUBIC facility manager.

CONFIDENTIALITY OF DATA

Data recorded at RUBIC will not contain any personal identifying information about participants. This applies to MRI images as well as all ancillary data such as behavioral or physiological responses. The researcher can, however, store a unique code in these data files. Participant's data will be associated with this code, which is secured by the researcher in a different database or physical location, and available only to those directly associated with the research study.

MINIMIZING DISCOMFORT

Each participant will be provided with ear protection. Subjects will be given their choice of single use, disposable foam earplugs (SNR 37dB, NRR 32dB) or passive ear muffs (NRR 33) while in the scanner to dampen the sound associated with the imaging process. Participants will be provided with a light blanket if they find the scanner room too cool. Padding and/or pillows will be provided to allow the participant to lie comfortably on the scanning table. To minimize head motion, researchers may use various levels of head-restraint. Depending on the acceptable level of head motion, subjects' heads will be stabilized using padding around the head, a strap across the head, a mold custom-fit to the head, or a bite bar. These procedures are discussed during the consent process and explained again when the participant is placed in the scanner.

MONITORING

While in the scanner, participants' behavior may be monitored using video monitoring, button boxes

(including a track ball, mouse, and data gloves), an infrared eye tracker, electro-oculograms (EOG), and physiological measures such as heart rate, electroencephalogram (EEG), respiration, and skin conductance.

EMERGENCY PROCEDURES

In the event of an emergency (e.g., medical, fire) procedures outlined in Appendix C will be followed. These Emergency Procedures will be prominently displayed on the wall of the control room.

TRAINING

Before scanning, all researchers at RUBIC will have to complete MRI safety training. Researchers operating the MRI scanner will additionally undergo operator training. See Appendix D for details. Appendix E is a sample safety quiz. [Appendix E will not be posted on the website with these common practices]

CONSENT FORM

A consent form template to be used with MRI studies is shown in Appendix F.

Appendix A (page 1 of 2)

MAGNETIC RESONANCE (MR) PROCEDURE SCREENING FORM

Date _____/_____/_____ Male Female Subject ID# _____

Study Title: _____ Researcher _____
First name - Middle Initial - Last name

No Yes 1. Have you experienced any problem related to a previous MRI examination or MR procedure?

If yes, please describe: _____

No Yes 2. Have you had an injury to the eye involving a metallic object or fragment (e.g. metallic slivers, shavings, foreign body, etc.)?

If yes, please describe: _____

No Yes 3. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)?

If yes, please describe: _____

<u>For female patients:</u>

No Yes N/A 4. Are you pregnant or think you may be pregnant?

The following items may be harmful to you in an MR setting or may interfere with image quality.

Please circle a "yes" or "no" for every item as appropriate.

Yes	No	Aneurysm clip(s)
Yes	No	Cardiac pacemaker
Yes	No	Implanted cardioverter defibrillator (ICD)
Yes	No	Electronic implant or device
Yes	No	Magnetically-activated implant or device
Yes	No	Neurostimulation system
Yes	No	Spinal cord stimulator
Yes	No	Internal electrodes or wires
Yes	No	Bone growth/bone fusion stimulator
Yes	No	Cochlear, otologic, or other ear implant
Yes	No	Insulin or other infusion pump or device
Yes	No	Any type of prosthesis (eye, penile, etc.)
Yes	No	Eyelid spring or wire
Yes	No	Artificial or prosthetic limb
Yes	No	Metallic stent, filter, or coil
Yes	No	Any metallic fragment or foreign body (e.g., shrapnel, metal filings, bullets)
Yes	No	Wire mesh implant
Yes	No	Surgical staples, clips, or metallic sutures
Yes	No	Bone/joint pin, screw, nail, wire, plate, etc.
Yes	No	Metallic removable dental work, braces, retainers
Yes	No	Tattoo or permanent makeup
Yes	No	Body piercing jewelry (must be removed before scanning)
Yes	No	Hearing aid (must be removed before scanning)
Yes	No	Claustrophobia
Yes	No	Heart valve prosthesis
Yes	No	Joint replacement (hip, knee, etc.)
Yes	No	Underwire bra
Yes	No	Other implant _____

_____ ____/_____/_____

Signature of Participant Date

_

_____

Printed Name: First Middle Last

Appendix B

PREGNANCY TEST RELEASE FORM

INFORMED CONSENT CONCERNING POTENTIAL PREGANCY for MRI STUDY

STUDY NAME: [_____fill in_____]

This release is to inform you that Magnetic Resonance Imaging (MRI) may pose a hazard to an unborn child/fetus although there are no reports of injury to children who underwent MR imaging before birth.

By signing this form, you are acknowledging that you have been warned of potential risk to an unborn child/fetus and have been offered a pregnancy test to determine if you are pregnant before being scanned.

Although you are encouraged to take the offered pregnancy test, it is your right to refuse. You may also decide to withdraw from this study if you so choose rather than take the pregnancy test.

This release documents that you have been offered a pregnancy test before participating in this study and have chosen to decline.

_____ _____/_____/_____
Signature of Person giving consent Date

_____
Printed Name: First Middle Last

_____
Signature of Witness to Person giving consent

_____
Printed Name: First Middle Last

Appendix C

Emergency Procedures for Human Studies at RUBIC

Medical Emergency Procedure (to be followed in the order listed)

1. The MRI operator/designee will remove the research participant from the magnet bore.

2. The MRI operator/designee will free the participant from coils and all immobilization devices.

3. The MRI operator/designee will remove the research participant from the magnet room and take him/her to the control room.

4. The MRI operator/designee will lock the magnet room door.

5. The MRI operator/designee will call 911 (this is the emergency number for Rutgers University) to request emergency medical service (EMS) at Aidekman Research Center located at 197 University Avenue, on the corner of Warren and University Avenue.

6. The MRI operator/designee will call Rutgers security at (973) 353-5111 and tell them EMS will be directed to the Aidekman Research Center on the corner of Warren and University Avenue.

7. The MRI operator/designee will alert the RUBIC Executive Committee and/or Facility Manager that there is a potential emergency.

8. No therapeutic procedures will be initiated until the subject is moved out of the scan room to the control room.

9. No equipment will be brought into the scan room.

10. The RUBIC staff or research personnel will cede responsibility to emergency responders and provide assistance as requested but ensure that no one enters the magnet room without screening.

11. After the emergency, the MRI operator/designee will report the adverse event to the Rutgers IRB and RUBIC executive committee.

MRI System Quench – Emergency Magnet Run-Down

A magnet quench quickly dissipates the scanner'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 equipment. 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.

1. Start quench by engaging 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.
2. Evacuate the magnet room and control room
3. Notify Rutgers security at (973) 353-5111
4. Notify Siemens of the quench
5. File incident report and notify appropriate University personnel.

Electrical Fire

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

Evacuation Procedure

1. The MRI system operator will lock the door to the magnet room.
2. In case of fire alarm activated in or near the RUBIC suite, a member of the RUBIC staff will contact Rutgers Security at (973) 353-5111 so that they can implement the appropriate Rutgers response procedure.
3. All personnel are to evacuate the building through the lobby of Aidekman Research Center.
4. No one will be allowed to reenter the building until granted permission by the Fire Department.

Incident Reports

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

4. Reports should be submitted internally to the RUBIC within 24 hours of the incident. RUBIC reports to other bodies, such as the relevant IRBs should occur within three (3) business days. Copies of the reports to the relevant IRBs will go to the following Rutgers offices:
    - Rutgers Administration and Public Safety (APS)
    - Rutgers Office of the Vice President for Research and Graduate and Professional Education

Appendix D (1 of 2)

RUBIC TRAINING PROCEDURES

Safety Training

Safety training is **required** for **all** research personnel who will be accessing the RUBIC facility in the course of their research. The objective of MRI safety/system operation training is to ensure the safe operation of the MRI research facility, to protect volunteers, research personnel and staff in the daily operation of the MRI scanner. These guidelines are designed to prevent accidents due to interactions with the MRI system. Recertification is required every two years.

There will be three levels of access to the RUBIC facilities: Basic, Advanced, and Operator. These levels and training details are described more fully below. Designated personnel will be responsible for assuring that individuals have achieved the appropriate level of training commensurate with level of access. Determination that an individual is qualified for a given level of access will involve testing (Levels 1 and 2) and observation of the individual's performance (Levels 2 and 3).

There are three levels of training associated with the three levels of access:

Level 1 – Basic Safety Training

Level 1 training provides the knowledge necessary to ensure one's own safety during research-related activities within the MRI suite. Persons with Level 1 training do not require escort within the MRI suite, but they may not enter the scan room without the approval of the scanner operator. Level 1 individuals may not be responsible for escorting participants or visitors nor are they permitted to handle MRI research equipment. All trainees will complete the clinical screening questionnaire completed by participants prior to scanning. Basic MRI Safety Training requirements:

- View Siemens MRI Safety orientation DVD "The Perfection of Care"
- Review RUBIC Policies and Procedures
- Complete MRI Safety Quiz (sample attached for review and then deleted)
- Review from Huettel; Functional Magnetic Resonance Imaging, Chapter 2, Section "MRI Safety" pp. 39-48.
- Review RUBIC emergency response procedures in the event of evacuation due to fire, quench, or other emergency events.

Level 2 – Advanced Safety Training

Level 2 training builds on Level 1 training, providing additional knowledge to protect the safety of others and to safely handle MRI related research equipment. Level 2 personnel are permitted to escort participants with the approval of the scanner operator. It is expected that most personnel routinely involved in research activities at RUBIC will complete Level 2 training. Advanced MRI Safety Training requirements:

- All components of Level 1 Training, plus
- Read following sections in the Siemens Operator Manual:

1. Section A – Safety: A.1 General Safety Information; A.2 Personal Safety Information; and A.3 Device-Related Safety Information in Siemens Operator Manual
2. Section B – MR System Components: B.6 Control Unit; B.7; Laser Light Localizer; B.8 Alarm Box; B.9 Intercom; B.10 Patient Table
3. Section D – MR System Operation: D.5 Physiological Effects

- Orientation to subject preparation (securing valuables, execution of screening form and consent forms, explanation of MRI scan process)
- Orientation to MRI scan room and MRI equipment (Scan room door overrides, table controls, intercom, emergency squeeze ball, linen, storage and use of RF coils)
- Emergency Procedures Training**:** instruction in procedures related to emergency situations involving medical emergencies or those presenting an immediate threat to human life or to the facility infrastructure. Orientation to location of Siemens Quench and Emergency Run-Down buttons, and the procedure for the evacuation of a subject during an adverse event. Review of evacuation plan.

Level 3 – Scanner Operator Training

Level 3 training builds on Level 1 and 2 training and provides the additional knowledge necessary for independent operation of the MRI system. Level 3 personnel have access to all areas of the MRI suite and, when operating the scanner, are responsible for the safety of research personnel, participants and visitors. Scanner Operator training is available to advanced graduate students, post-docs, faculty and certain other individuals at the discretion of the administration. Undergraduates may not operate the scanner. MRI Scanner Operation Training requirements:

- Minimum 6 hours of shadowing Level 3 RUBIC personnel performing magnet operations
- Overview of MRI system start-up and shutdown procedure
- Orientation of MR equipment room, O2 connections, vacuum valve, immobilization pillows, ear protection, head coil and mirror
- Supervised execution of routine scanning procedures

Testing

Following Level 1 training, an exam to evaluate the applicant's knowledge of MRI safety will be administered and scored by designated personnel. An example of the type of exam to be used is shown in Appendix E (deleted prior to posting). A score of 90% will be required to pass. If the applicant does not pass this exam, he/she will be required to redo Basic Training and to re-take a comparable exam. A similar testing procedure will be used to evaluate Level 2 training with the addition that designated personnel will verify that the individual is familiar with the physical components associated with Level 2 access. Level 3 access will be granted if the RUBIC Executive Committee believes the individual to be capable of independent scanner operation following the six hours of supervised scanning.

Appendix E

Sample MR Safety Quiz (not posted)

Appendix F (1 of 3)

Consent to Participate in a Research Study

TITLE OF STUDY: [insert]

RESEARCH STUDY: You have been asked to participate in a research study under the direction of _____. Other individuals working as co-investigators or study staff may assist or act for the primary investigator.

PROCEDURES: [Study specific details, **fill in**; this section might include something like: you will be asked a series of screening questions and then scanned for metal. When you enter the MRI suite you will put on ear phones or plugs, lie on table, enter a noisy small tube, and remain still for about **XXX** minutes.
Note: if you ask participants to wear goggles or anything, you must include here. You must also include some detail if they are exposed to visual or auditory stimuli, specific to your study.]

PARTICIPANTS: You will be one of a group of about _xxx_ individuals to participate in this study.

EXCLUSIONS: You cannot participate in this study if any of the following apply:

- you have any magnetic metal such as iron, nickel or cobalt implanted in or on your body or clothes including metal flakes or filings, surgical pins or plates, electrical devices such as a pace maker, jewelry, or metal ink tattoos.
- you are pregnant
- you are claustrophobic or anxious in small spaces

RISKS AND DISCOMFORTS: The following risks and/or discomforts are possible:

- Feelings of claustrophobia can occur in the scanner. If you experience feelings of claustrophobia please alert the researcher and you will be removed from the scanner immediately.

- There is considerable background noise generated by the magnet. You will be given your choice of earplugs or ear muffs to reduce the noise, but you should alert the researcher if you find the noise too uncomfortable and you will be removed from the scanner immediately.

BENEFITS: Your participation will greatly increase knowledge about the brain and the cognitive processes underlying human behavior.

PAYMENT FOR PARTICIPATION: [Study specific input, **fill in**; this would include credit for participation such as a subject pool and/or monetary incentives, specific to your study**]**

Subject Initials _____

RIGHT TO WITHDRAW: Your participation is voluntary, and you may refuse to participate, or may discontinue your participation at any time, without penalty or loss of benefits to which you are otherwise entitled. The investigator also has the right to withdraw you from the study at any time if necessary. Should you withdraw or be withdrawn, you will receive reduced compensation proportionate to your level of participation before withdrawal.

CONFIDENTIALITY: You give permission for the scientific use of your data. If the data from the study are published, or made part of an archive or database accessible to individuals other than the investigators and their collaborators your data will never be associated with any identifying characteristics such as: name, address, social security or other identifying number, or any combination of data about you which could reasonably lead, directly or indirectly by reference to other information, to your identification. The researcher will, however, associate a unique code with your data files. This code will be secured by the researcher in a different database or physical location, and available only to those directly associated with the research study.

FINANCIAL COSTS TO THE PARTICIPANT: There is no cost to you for participating in this study.

INDIVIDUAL(S) TO CONTACT: If you have any questions about your treatment in this study, you can contact:

Name : ___[fill in]_____
Address:
___[fill in]_____
___[fill in]_____
___[fill in]_____
Tel #: ___[fill in]_____
Email: ___[fill in]_____

If you have any questions about your rights as a research participant, you can contact the Rutgers Office of Research and Sponsored Programs:

Rutgers University Institutional Review Board
Office of Research and Sponsored Programs
3 Rutgers Plaza
New Brunswick, NJ 08901-8559
Tel: 732-932-0150 ext. 2104
Email: humansubjects@orsp.rutgers.edu

Subject Initials _____

SIGNATURE OF SUBJECT: Please acknowledge that you have read and understand this entire form and that any questions regarding this form or this study have been answered to your satisfaction. If you would like a copy of this form, it will be provided to you. You agree to participate in this research study.

Print Name: _____ Signature:_____

Date: ____/____/_____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL: To the best of my knowledge the subject whose name is entered above has understood the above consent form, and the participant's questions have been accurately answered to his/her satisfaction.

Print Name: _____ Signature:_____

Date: ____/____/_____