MRI Protocol Test and Optimization Appendix

Use with any protocols including MRI scanning

Based off MRI general protocols:

IRB 10-269 MR 1010 - 3T MRI Protocol Test and Optimization

IRB 12-111 MR 1203 - 7T MRI Protocol Test and Optimization

MRI Recruitment / Advance Screening Form

Revised 9/17/2018

Auburn University MRI Research Center
560 Devall Drive Suite 202
Auburn, AL 36849
Tel: (334) 844-6747 Fax: (334) 844-0214

This form to be used for: Recruiting and initial screening of research subjects prior to arrival at the AU MRI Research Center

1. ☐Yes ☐No Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind where a device was implanted? If yes, please describe_____
2. ☐Yes ☐No Have you had any medical condition that prevented you completing an MRI exam in the past or had any related to a previous MRI examination or procedure? If yes, please describe: _____
3. ☐Yes ☐No Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? If yes, please describe: _____

WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the AU MRI Research Center staff BEFORE entering the MR system room. **The MR system magnet is ALWAYS on.**

Answering "Yes" to any of the following questions excludes the subject from the study

4. ☐Yes ☐No Do you have a cardiac pacemaker or implanted cardioverter defibrillator (ICD)?
5. ☐Yes ☐No Is there a possibility of metal in your head (for example aneurysm clips, do not include dental work)? If yes, please describe: _____
6. ☐Yes ☐No Have you had an injury to the eye involving a metallic object or fragment (for example, metallic slivers, shavings, foreign body), or have you ever needed an eyewash having worked with metals? If yes, please describe: _____
7. ☐Yes ☐No Do you have an implanted medical device that is electrically, magnetically, or mechanically controlled or activated (see examples below)? If yes, please describe: _____
8. ☐Yes ☐No **Females Only**: Are you pregnant or is there any possibility that you may be pregnant?

Protocol-Specific Questions (Answering "Yes" to any of the following questions may exclude the subject from the study)

9. ☐Yes ☐No Do you have braces?
10. ☐Yes ☐No Do you have a breathing problem or motion disorder?
11. ☐Yes ☐No Are you claustrophobic?
12. ☐Yes ☐No Do you have inner ear disorders or experience vertigo or dizziness?
13. ☐Yes ☐No Do you have tattoos or permanent makeup that contains metal?
14. ☐Yes ☐No Do you have body piercing jewelry that cannot be removed?

Examples of implanted medical devices

Neurostimulation system *	Shunt (spinal or intraventricular)
Spinal cord stimulator *	Vascular access port and/or catheter
Internal electrodes or wires *	Radiation seeds or implants
Bone growth/bone fusion stimulator *	Swan-Ganz or thermodilution catheter
Cochlear, otologic, or other ear implant	Medication patch (Nicotine, Nitroglycerine)
Insulin or other infusion pump	Any metallic fragment or foreign body
Implanted drug infusion device	Wire mesh implant
Any type of prosthesis (eye, penile, etc.)	Tissue expander (e.g., breast)
Heart valve prosthesis	Surgical staples, clips, or metallic sutures
Eyelid spring or wire	Joint replacement (hip, knee, etc.)
Artificial or prosthetic limb	Bone/joint pin, screw, nail, wire, plate, etc.
Metallic stent, filter, or coil	IUD, diaphragm, or pessary

* If these implanted medical devices are present, the subject cannot be scanned

MRI Pre-Entry Screening Form

Revised 6/13/2024

Auburn University MRI Research Center
560 Devall Drive Suite 202
Auburn, AL 36849
Tel: (334) 844-6747 Fax: (334) 844-0214

This form to be used for: Screening of research subjects immediately prior to an MRI study (File completed form with Principal Investigator)

Name _____
Last First MI

Address _____ City _____

State _____ Zip Code _____ Male/Female_____

Phone (___)_____ (___)_____ (___)_____
Home Work Cell

Birthdate _____ Email Address _____

Primary Physician (Optional):

Name_____ Phone (___)_____

AUMRIRC Use Only

Principal Investigator: _____

IRB Protocol # _____

Subject # _____

Date/Time of MRI study ___/___/_____ ___:___

☐ 3T MRI Subject Weight (lbs) _____

☐ 7T MRI Height(ft/in) _____

1.	☐Yes ☐No	Have you had prior surgery or an operation of any kind? If yes, give date and type of surgery, and indicate where on your body using the diagram. Date: __/__/____ Type of surgery: _____ Date: __/__/____ Type of surgery: _____ Date: __/__/____ Type of surgery: _____
2.	☐Yes ☐No	Have you had any medical condition that prevented you completing an MRI exam in the past or had any related to a previous MRI examination or procedure? If yes, please describe: _____
3.	☐Yes ☐No	Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? If yes, please describe: _____

WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the AU MRI Research Center staff BEFORE entering the MR system room. **The MR system magnet is ALWAYS on.**

Answering "Yes" to any of the following questions excludes you from the study

4.	☐Yes ☐No	Do you have a cardiac pacemaker or implanted cardioverter defibrillator (ICD)?
5.	☐Yes ☐No	Is there a possibility of metal in your head (for example aneurysm clips, do not include dental work)? If yes, please describe: _____
6.	☐Yes ☐No	Have you had an injury to the eye involving a metallic object or fragment (for example, metallic slivers, shavings, foreign body), or have you ever needed an eyewash having worked with metals? If yes, please describe: _____
7.	☐Yes ☐No	Do you have an implanted medical device that is electrically, magnetically, or mechanically controlled or activated? If yes, please describe: _____
8.	☐Yes ☐No	**Females Only**: Are you pregnant or is there any possibility that you may be pregnant?

Protocol-Specific Questions (Answering "Yes" to any of the following questions may exclude you from the study)

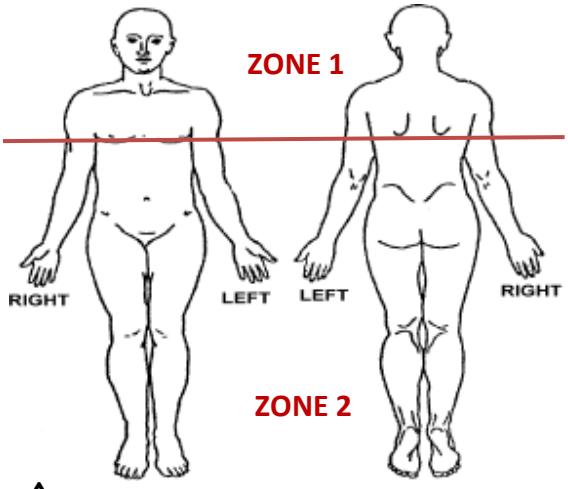
9.	☐Yes ☐No	Do you have a history of cardiovascular disease?
10.	☐Yes ☐No	Do you have a breathing problem or motion disorder?
11.	☐Yes ☐No	Are you claustrophobic?
12.	☐Yes ☐No	Do you have inner ear disorders or experience vertigo or dizziness?
13.	☐Yes ☐No	Do you have tattoos or permanent makeup that contains metal?
14.	☐Yes ☐No	Do you have body piercing or any jewelry that cannot be removed?
15.	☐Yes ☐No	Do you have braces, retainers, or dental work other than fillings and crowns?

WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the AU MRI Research Center staff BEFORE entering the MR system room. **The MR system magnet is ALWAYS on.**

Please indicate if you have any of the following (check diagram for zones):

16.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Neurostimulation system
17.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Spinal cord stimulator
18.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Internal electrodes or wires
19.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Bone growth/bone fusion stimulator
20.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Cochlear, otologic, or other ear implant
21.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Insulin or other infusion pump
22.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Implanted drug infusion device
23.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Any type of prosthesis (eye, penile, etc.)
24.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Heart valve prosthesis
25.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Eyelid spring or wire
26.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Artificial or prosthetic limb
27.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Metallic stent, filter, or coil
28.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Shunt (spinal or intraventricular)
29.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Vascular access port and/or catheter
30.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Radiation seeds or implants
31.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Swan-Ganz or thermodilution catheter
32.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Medication patch (Nicotine, Nitroglycerine)
33.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Any metallic fragment or foreign body
34.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Wire mesh implant
35.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Tissue expander (e.g., breast)
36.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Surgical staples, clips, or metallic sutures
37.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Joint replacement (hip, knee, etc.)
38.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Bone/joint pin, screw, nail, wire, plate, etc.
39.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	IUD, diaphragm, or pessary
40.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Dentures or partial plates
41.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Permanent retainer, braces, or dental work other than fillings and crowns
42.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Tattoo or permanent makeup
43.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Body piercing jewelry
44.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Hearing aid (*Remove before entering MRI scanner room)*
45.	☐Yes, Zone 1	☐Yes, Zone 2	☐No	Other implant: _____

Please mark on the figure(s) below the location of any implant or metal inside of or on your body.



IMPORTANT INSTRUCTIONS

Before entering the MR scanner room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clippers, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the research staff if you have any question or concern BEFORE you enter the MR scanner room.

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

If you answered yes to any of the above, please provide the following information if known: the approximate size of the implant, whether or not it is removable, and whether or not it is metallic: _____

_____

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

This form is valid only on the day it is completed.

Signature of Person Completing Form: _____
Signature Date

Form Completed By: ☐ Subject ☐ Relative _____ _____
Print Name Relationship to Subject

Form Information Reviewed By: _____ _____
Print Name Signature

Form Information Reviewed By: _____ _____
Print Name Signature

MRI Environment Screening Form for Individuals*

Revised 9/17/2018

Auburn University MRI Research Center
560 Devall Drive Suite 202
Auburn, AL 36849
Tel: (334) 844-6747 Fax: (334) 844-0214

This form to be used for: Screening of non-MRI personnel who wish to enter the MRI scanner room but will not undergo an MRI examination (File completed form with AUMRIRC)

The MR system has a very strong magnetic field that may be hazardous to individuals entering the MR environment or MR system room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. Therefore, all individuals are required to fill out this form BEFORE entering the MR environment or MR system room. **Be advised, the MR system magnet is ALWAYS on.**

***NOTE: If you are a patient preparing to undergo an MR examination, you are required to fill out a different form.**

1. ☐Yes ☐No Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind where a device was implanted? If yes, please describe: _____
2. ☐Yes ☐No Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? If yes, please describe: _____
3. ☐Yes ☐No Do you have a cardiac pacemaker or implanted cardioverter defibrillator (ICD)?
4. ☐Yes ☐No Is there a possibility of metal in your head (for example aneurysm clips, do not include dental work)? If yes, please describe: _____
5. ☐Yes ☐No Have you had an injury to the eye involving a metallic object or fragment (for example, metallic slivers, shavings, foreign body), or have you ever needed an eyewash having worked with metals? If yes, please describe: _____
6. ☐Yes ☐No Do you have an implanted medical device that is electrically, magnetically, or mechanically controlled or activated (see examples below)? If yes, please describe: _____

WARNING: Certain implants, devices, or objects may be hazardous to you in the MRI environment or MRI scanner room. Do not enter the MRIenvironment or MRI scanner room if you have any question or concern regarding an implant, device, or object. **The MR system magnet is ALWAYS on.**

Please indicate if you have any of the following:

Neurostimulation system	Shunt (spinal or intraventricular)
Spinal cord stimulator	Vascular access port and/or catheter
Internal electrodes or wires	Radiation seeds or implants
Bone growth/bone fusion stimulator	Swan-Ganz or thermodilution catheter
Cochlear, otologic, or other ear implant	Medication patch (Nicotine, Nitroglycerine)
Insulin or other infusion pump	Any metallic fragment or foreign body
Implanted drug infusion device	Wire mesh implant
Any type of prosthesis (eye, penile, etc.)	Tissue expander (e.g., breast)
Heart valve prosthesis	Surgical staples, clips, or metallic sutures
Eyelid spring or wire	Joint replacement (hip, knee, etc.)
Artificial or prosthetic limb	Bone/joint pin, screw, nail, wire, plate, etc.
Metallic stent, filter, or coil	IUD, diaphragm, or pessary

IMPORTANT INSTRUCTIONS

Before entering the MR scanner room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clippers, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the research staff if you have any question or concern BEFORE you enter the MR scanner room.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form.

Printed Name of Person Completing Form: _____
Print Name

Signature of Person Completing Form: _____
Signature Date

Form Information Reviewed By: _____ _____ _____
Print Name Signature Date

Auburn University MRI Research Center

Instructions for MRI Screening Forms

Which Form to Use

- MRI Subject Recruitment / Advance Screening Form
    - Used for pre-screening subjects via telephone, meeting outside MRI Center, or email before they are invited to the site to determine if they have any contraindications for an MRI scan stated in the IRB protocol.
    - This form does not contain any identifiable information
- MRI Pre-Entry Screening Form
    - Used for subjects that will undergo an MRI scan and those (for example parents) that accompany them.
    - This form is completed by the subject or his/her representative (e.g. parent).
    - Valid only for the day it is completed.
    - Must be signed by subject and two separate screeners.
    - File this form with the project principal investigator (PI).
- MRI Environment Screening Form for Individuals
    - Use this form for individuals wishing to enter Zone IV (MRI scanner room) but will not undergo an MRI scan.
    - This form is completed by the individual wishing to enter the MRI environment.
    - Questions on the MRI Subject Recruitment / Advance Screening Form and MRI Pre-Entry Screening Form may not be appropriate for those just wishing to enter the scanner room.
    - File this form with the AU MRI Research Center administrative office.

Instructions for MRI Subject Recruitment / Advance Screening Form

- **Subject information**
    - The MRI Subject Recruitment / Advance Screening Form does not contain identifiable information about the subject**.**
- **Questions 1 – 3:** These questions are needed to help determine if there is a device, implant, injury, or any other problem that could cause a problem with the MRI scan or pose a risk to the subject's safety in the MRI environment.
- **Questions 4 – 8:** Answering "Yes" to any of these questions is an absolute contraindication for MRI. The subject should not be scanned, scheduled for a scan, or allowed into the MRI scanner room.
- **Questions 9 – 14:** Answering "Yes" to any of these questions is not a contraindication for MRI, but special procedures (described in the IRB-approved research protocol) must be followed to prepare the subject for imaging and the subject must be carefully monitored during the scan.

- Body piercing jewelry should be removed before entering the MRI scanner room. If it cannot be removed the subject cannot be scanned.
- The subject must be informed that if they have tattoos or permanent makeup, there is some risk of burns, and that they should ask to stop the scan if any burning sensation is felt. Ice packs or cold compresses may be prospectively placed on any tattoos before the scan if it is practical to do so.
- Subjects with claustrophobia, motion disorders, or breathing problems may need training on a mock scanner (if possible) or other training to adapt to the imaging process before scanning.

- **Examples of implanted medical devices:**
  - If the subject has any of the first four of these implanted devices marked with an asterisk is an absolute contraindication for MRI. The subject should not be scanned, scheduled for a scan, or allowed into the MRI scanner room.
  - If the subject has any of these devices (excluding top four with asterisks) it may be a contraindication for MRI depending on the IRB-approved research protocol in effect and which scanner is being used.
    - For 3T MRI scans, the subject can be scanned with IRB approval if the type, manufacturer, and location of the device can be documented and the device is MR safe or MR conditional for the scanning protocol being used.
    - For 7T MRI scans, participants with non-ferrous, but metallic implants may be imaged if the following conditions are met.
      - The implant is MR Conditional at 3T or MR Safe.
      - The implant is located more than 30cm away from the transmit coil (Zone 2 on the Pre-Entry Screening Form).
      - The implant's largest dimension is less than 14cm. Implant documentation, if available, will be used to determine the largest dimension of the implant. If implant documentation is not available, the participant will self-report what the implant is. If the implant is clearly 14cm or less (for example, an ankle screw), it will be allowed. If the implant is of unknown size, or is clearly 14cm or longer, then it will be disallowed.
      - The implant is not programmable (e.g. defibrillators, pacemakers, deep brain stimulation devices)
      - The implant is not in the brain
      - Please refer to the MRISAC 7T MRI Implant Policy for more details.

- **Names/Signatures**
  - The MRI Subject Recruitment / Advance Screening Form does not require signatures by the subject or screeners.

Instructions for MRI Pre-Entry Screening Form

- **Subject information**
  - Completed by screener and scanner operator.
- **AUMRIRC Use Only**
  - Completed by investigator
- **Questions 1 – 3:** These questions are needed to help determine if there is a device, implant, injury, or any other problem that could cause a problem with the MRI scan or pose a risk to the subject's safety in the MRI environment.
- **Questions 4 – 8:** Answering "Yes" to any of these questions is an absolute contraindication for MRI. The subject should not be scanned, scheduled for a scan, or allowed into the MRI scanner room.
- **Questions 9 – 15:** Answering "Yes" to any of these questions is not a contraindication for MRI, but special procedures (described in the IRB-approved research protocol) must be followed to prepare the subject for imaging and the subject must be carefully monitored during the scan.
  - Body piercing jewelry should be removed before entering the MRI scanner room. If the jewelry cannot be removed, the subject cannot be scanned.
  - The subject must be informed that if they have tattoos or permanent makeup, there is some risk of burns, and that they should ask to stop the scan if any burning sensation is felt. Ice packs or cold compresses may be prospectively placed on any tattoos before the scan if it is practical to do so.
  - Subjects with claustrophobia, motion disorders, or breathing problems may need training on a mock scanner (if possible) or other training to adapt to the imaging process before scanning.

- **Questions 16 – 39:** Answering "Yes" to any of these devices may be a contraindication for MRI depending on the IRB-approved research protocol in effect and which scanner is being used.
  - For 3T MRI scans, the subject can be scanned with IRB approval if the type, manufacturer, and location of the device can be documented and the device is MR safe or MR conditional for the scanning protocol being used.
  - For 7T MRI scans, Participants with non-ferrous, but metallic implants may be imaged if the following conditions are met.
    - The implant is MR Conditional at 3T or MR Safe.
    - The implant is located more than 30cm away from the transmit coil (Zone 2 on the Pre-Entry Screening Form).
    - The implant's largest dimension is less than 14cm. Implant documentation, if available, will be used to determine the largest dimension of the implant. If implant documentation is not available, the participant will self-report what the implant is. If the implant is clearly 14cm or less (for example, an ankle

screw), it will be allowed. If the implant is of unknown size, or is clearly 14cm or longer, then it will be disallowed.
        - The implant is not programmable (e.g. defibrillators, pacemakers, deep brain stimulation devices)
        - The implant is not in the brain
        - Please refer to the MRISAC 7T MRI Implant Policy for more details.
- **Questions 40 - 46:** Answering "Yes" to any of these questions is not a contraindication for MRI, but special procedures (described in the IRB-approved research protocol) must be followed to prepare the subject for imaging and the subject must be carefully monitored during the scan.
    - Dentures, partial plates, body piercing jewelry, and hearing aids should be removed before entering the MRI scanner room.
    - The subject must be informed that if they have tattoos or permanent makeup, there is some risk of burns, and that they should ask to stop the scan if any burning sensation is felt. Ice packs or cold compresses may be prospectively placed on any tattoos before the scan if it is practical to do so.
    - Subjects with claustrophobia, motion disorders, or breathing problems may need training on a mock scanner (if possible) or other training to adapt to the imaging process before scanning.

- **Names/Signatures**
    - MRI Subject Recruitment / Advance Screening Form
        - The researcher completing the form prints their name, then signs and dates the form.
    - MRI Pre-Entry Screening Form
        - The subject (or representative) completing the form prints their name, then signs and dates the form.
        - The screener and scanner operator print their names and sign the form.

<u>Instructions for MRI Environment Screening Form for Individuals</u>

- **Personal information**
    - Name and contact information for the individual
- **Question 1:** This question is needed to help determine if there is a device, implant, injury, or any other problem that could pose a risk to the subject's safety in the MRI environment.
- **Question 2:** If the individual answers "Yes" to this question and there is a possibility that the object or part of the object is still in the body, the individual cannot enter the MRI scanner room.
- **Question 3-6:** If the individual answers "Yes" to any of these questions, the individual cannot enter the MRI scanner room. (Dental work is excluded for Question 4)
- **"Please indicate if you have any of the following" section:** Answering "Yes" to ANY these means the individual cannot enter the MRI scanner room.

- **Names/Signatures**
    - The individual requesting entry into the MRI scanner room must complete the form themselves, then sign and date the form.
    - A person with Level 2 training or higher must review the form, then print and sign their name before allowing the individual entry to the MRI scanner room.

MRI Protocol Test and Optimization

Research Protocol

- Before subject arrives at the AU MRI Research Center
    - Obtain IRB approval for your scanning protocol
    - Pre-screen subject via telephone, meeting outside MRI Center, or email before they are invited to the site to determine if they have any contraindications for an MRI scan stated in the IRB protocol. If contraindications are found, the subject must not be scanned.
        - Use the MRI Subject Recruitment / Advance Screening Form
            - File this form with the principal investigator
        - If subject answers "Yes" to any of questions 4-8, the subject has absolute contraindications for MRI and cannot be scanned.
    - Schedule the scan with the AU MRI Research Center administrative office.
    - Inform all subjects that being scanned requires the subject to change out of their own clothes into scrubs provided by the MRI Center. Also inform female participants that the individual cannot wear a bra that has any metal underwire during the scan.
- Pre-scan Procedure
    - The participant is consented and screened using the procedure described in the IRB protocol.
    - The investigator escorts the participant to the dressing room, where the participant changes into AU MRI Research Center supplied clothing (surgical scrubs).
    - The participant is reminded to use the restroom if needed.
    - The participant is screened a second time by someone different than the person who conducted the first screening. The second screener must have Level 2 training or higher.
        - The participant is scanned with the handheld ferromagnetic metal detector.
            - If a ferromagnetic object is detected, it must be removed and stored with the participants other belongings.
            - If ferromagnetic object cannot be removed, the participant must not be scanned.
                - The investigator must explain why they cannot be scanned and that it is no cause for alarm. The investigator should also point out that rejection as a research participant does not necessarily mean that a future MRI scan for medical purposes would be unsafe, and that they should follow the recommendations of medical personnel in such a situation. The participant is then allowed to change back into their normal clothes and escorted out of the MRI suite.
    - The participant is asked again to make sure they have removed the following

Watch	Hearing aid
Jewelry	Removable dentures
Hair pins / barrettes	Nicotine or other patch
Piercings	Clothing with metal (underwire bra)
Glasses	Any implant held in place by a magnet

  - If a participant wears glasses, they will be supplied with MRI safe glasses at their prescription if requested or if required by the scanning protocol. The glasses prescription is measured by the focimeter located in the scanner console room.
  - The second screener must also review and sign the MRI Pre-Entry Screening Form.
  - The participant must be weighed facing outward from the scales. The weight is entered into the Pre-Entry Screening Form without comment on the weight. This weight is an MRI SAR safety parameter that is required by the scanner registration before a scan can begin.
  - The participant will be asked to stand against a height chart hanging on the wall to measure their height. The height is entered into the Pre-Entry Screening Form.
  - The investigator will place a clean linen sheet to cover the scanner table prior to each scan. The head coil is wiped down prior to each scan. If the head coil is not being used the investigator places a clean linen pillowcase on a pillow and places that on the scanner table.
- Scanning Procedure
  - The scanner can only be operated by someone with Level 3 training.
  - At least two people in addition to the participant are required to be present at the console during a scan.
    - At least one of these people is the scanner operator who must have Level 3 training. The other person must have at least Level 2 training.
  - One person with at least Level 2 training must be designated as the safety officer for the scan. This person's name must be entered in the Research Scan Log book, and this person is responsible for all safety issues during the time the research participant is in Zone III and Zone IV. The designation of a single safety officer for each scan ensures a clear line of authority during an emergency.
  - Ear protection must be issued to each participant before they are inserted into the scanner bore. The type of ear protection is determined by the IRB-approved scanning protocol, and can include
    - Disposable earplugs
    - Earphones used for fMRI studies or in-bore patient entertainment
  - The participant must be informed that if they have tattoos , there is some risk of heating, and that they should ask to stop the scan if any heating sensation is felt. If a participant reports a heating sensation near the site of the tattoo during a scan, the scan will be stopped and the participant will be removed from the scanner and removed from the study.
  - The participant is asked to slowly lie down on the scanner table.

- Insulating foam may be placed between the participant and the scanner at any points where the participant's body touches the scanner bore or RF coil.
- The participant's weight from the Pre-Entry Screening form is entered into the scanner without comment on the weight.
- If a cardiac scan is being performed, a researcher will ask the participant if they have ever had an allergic reaction to an adhesive patch. If the participant has had an allergic reaction, the patches will not be applied and an FDA-approved Siemens optical pulse sensor attached to an index finger will be used instead to trigger the scanner. If the participant has not had an allergic reaction, a researcher will apply electrocardiogram (ECG) patches to the subject's chest and connect an FDA-approved Siemens ECG transmitter to the patches. The body of the transmitter will be placed in a foam holder and onto the subject's abdomen. A towel will be placed between the ECG wires and transmitter and the subject's chest. This procedure will be performed by a male researcher for male participants and a female researcher for female participants.
- Prior to the start of the first scan, the participant is asked if they have any current health concerns such as nausea. If the answer is yes, the participant is slowly removed from the scanner and excused from the study.
- The participant is scanned with either a Food and Drug Administration (FDA) approved protocol, a Siemens-supplied Work in Progress (WIP) protocol, a Customer-to-Customer (C2P) imaging protocol, or AUMRISAC approved custom-written protocol.
    - The scanner operator must have Level 3 training.
    - Some participants may be asked to tap their fingers.
    - Some participants may be presented with visual or auditory stimuli during the scan and asked to push a button when certain conditions are met.
    - Some participants will be asked to take a deep breath, blow it out, and then hold their breath for 25 seconds or less. They will be asked to do this 30-40 times during a one hour scanning session, with approximately 30 seconds or more between breath holds.
- Direct visual observation of the participant by the scanner operator must be maintained at all times.
- The scanner microphone and speaker system are tested to ensure that there is two-way communication between the scanner operator and the participant.
- The participant is given a squeeze ball and is instructed that they can squeeze the ball and/or verbally tell the operator to stop and the scanning will be stopped immediately.
- Prior to performing each scan, the scanner operator will ask the participant if they are ready for the scan to be performed. If the answer is "no," the operator will ask if the participant would like a brief period of rest or if they would like to terminate the scan.
- If peripheral nerve stimulation (PNS) or any other adverse event is encountered at any time during the scan, fill out the Adverse Event form and submit it to the AU MRI Research Center Administrative office.
    - PNS or other adverse events do not necessarily mean that the scan should be terminated.
    - The scan can be terminated at any time at the request of the user.

        - Otherwise, the determination of whether or not to terminate the scan is determined by the designated safety officer for the scan in accordance with the applicable IRB protocol.
- Post-scan Procedure
    - After a cardiac scan, a researcher will remove the ECG transmitter and towel from the participant. This procedure will be performed by a male researcher for male participants and a female researcher for female participants. The participant will be informed that they need to remove the ECG patches when they change clothes and that removing the patches may cause a slight sting similar to removing a Band-Aid.
    - The participant is removed from the scanner and asked to rise to a sitting position slowly and to slowly remove themselves from the scanner table.
    - The participant is escorted to the dressing room and allowed to change back into their original clothing.
    - The participant is escorted out of Zone III and Zone II.
    - The investigator removes the linen sheet from the scanner table along with the pillowcase (if a pillow was used) and places them in the laundry bins outside the scanner suite for laundry services to pick up and clean.
    - The image data is anonymized using Siemens software and stored on a College of Engineering server under a randomly-generated code.
    - The imaging study is deleted from the scanner.
    - The Consent Form and MRI Pre-Entry Screening Form is filed with Julie Rodiek (Academic Programs Administrator) along with the randomly-generated code in the AU MRI Research Center administrative office.
    - Report any problems to Dr. Denney.
- Cleaning
    - AU MRI Research Center personnel with at least Level 1 training will perform the following cleaning tasks in the MRI scanner room.
        - Clean the scanner bore, table, and coils between clinical and experimental uses, between animal and human uses and following any contact with human or animal body fluids, or known infections with Clorox wipes or equivalent.
        - Sweep the scanner room floor once a week or following any animal scans with a Swiffer. Mop the scanner room floor following any contact with human or animal body fluids using an MRI safe mop and bucket.

MRI Protocol Test and Optimization

Risks and Discomforts

Principles of MR Imaging

There are three main component of the MRI scanner: the static magnetic field, the radiofrequency field, and the gradient or time varying magnetic field.

Static Magnetic Field

THE STATIC MAGNETIC FIELD IS ALWAYS ON. The static magnetic field is the main magnetic field that is always present once the scanner is ramped up to the designated field strength. This field is described in units of Tesla (T) or Gauss (1T = 10,000 Gauss). The scanner used in this research project uses either a 3T or 7T static magnetic field. A 3T static magnetic field is approximately 60,000 times stronger than the earth's magnetic field that induces a compass to point North. The distance for the magnet that is safe for the general public and to use all objects and devices is denoted as the 5 Gauss line.

Radiofrequency Field

The MRI scanner uses radiofrequency (RF) coils as transmitters to excite the MRI signal and as a receiver to detect the MRI signal. The radiofrequency (RF) coil is the main source of heating within the scanner.

Gradient/Time-varying Magnetic Field

The gradient or time varying magnetic field selects the slices and imaging planes. This particular field is superimposed over the static magnetic field, and is the sources of all the acoustic noise. The coils within this system are pulsed on and off to produce linear gradients of the magnetic field for imaging. This allows producing an array of images with different spatial and temporal resolutions, and with different contrast between tissues in the image.

Risks of MRI

Projectiles

Items that are ferromagnetic have the potential of becoming projectiles when introduced to the magnetic field. Objects with ferrous properties can rapidly accelerate toward the scanner when captured by the magnetic field. Projectiles can result in an individual being struck, injured or trapped against the magnet by the object. Projectiles have the potential to cause serious injury or even death, to anyone who may be in the path of the acceleration. In addition, the scanner may be irreparably damaged.

Torsion and Translation Forces

Ferromagnetic objects or devices will be attracted to the magnetic field. Ferrous objects such as brain aneurysm clips, metal fragments in the eyes, and/or implanted medical device within the body, will attempt to align themselves with the static magnetic field and cause tearing or other injury to surrounding tissue.

Vestibular Effect

Due to the field strength of the MRI scanner it is possible to undergo the effects of vertigo and nausea. These are all effects associated with the vestibular phenomena. This most often occurs when research participants make quick head movements while in the scanner. This is also a possible occurrence when research participants are moved from the magnetic field.

Peripheral Nerve Stimulation

The gradient/time-varying magnetic fields used in MRI can, in some cases, induce stimulation of peripheral nerves, which produces sensations such as "twitching" or "tingling." In rare cases, nerve stimulation can be painful. Nerve stimulation is particularly likely when a subject is position with their hands clasped or arms folded. It should be noted that peripheral nerve stimulation is caused by the change in magnetic field with time (dB/dt), which is not a function of the *static* magnetic field. As a result, evaluating the risk of peripheral nerve stimulation in a 3T and 7T scanner involves the same considerations as evaluating the risk of peripheral nerve stimulation in a lower field strength (e.g. 1.5T) scanner.

Acoustic Noise

During an MRI scan, the mechanical movement of gradient coils produces acoustic noise, which can cause discomfort.

Induced Currents and Electrical Interference

The magnetic and electrical fields used in an MRI scanner can induce currents in wires and circuitry and cause interference with implanted objects and devices that are electrically, magnetically, or mechanically controlled or activated. This interference can potentially cause these objects or devices to malfunction.

Radiofrequency Heating

The RF signals used in an MRI scan can cause an object to warm up. This is somewhat analogous to a microwave oven. In FDA-approved or Siemens Work-in-Progress scans, these warming effects, if they exist at all, are very minimal. For subjects with certain tattoos there is a risk of burns.

Suffocation

The static magnetic field is generated by a superconducting magnet that is cooled with liquid helium. In rare situations (called as quench, see Emergency Procedures) the superconducting magnet could malfunction and release a large amount of helium gas. Under normal circumstances, this helium gas will be vented through the roof of the facility. If the ventilation system fails, the released helium will rapidly force all of the oxygenated air out of the scanner room, which could suffocate personnel inside the scanner room.

Heating of Tattoos

It is possible that the magnetic fields generated by the MRI scanner can interact with tattoos and cause warming at the site of the tattoo. More severe heating can occur if the tattoo contains metal fragments or the tattoo ink contains iron oxide or other metals.

Claustrophobia

Some participants experience claustrophobia when inside the MRI scanner bore.

Nausea

During an MRI scan, some participants can become nauseous either due to the vestibular effect described above when being inserted or removed from the scanner, anxiety, or other reasons. It is possible for a participant to vomit while they are in the scanner.

Allergic Reaction to Adhesive ECG Patches

Some participants may have an allergic reaction to adhesive electrocardiogram (ECG) patches applied to the chest prior to a cardiac MRI scan.

Emotional Discomfort

It is possible that a previously unknown abnormality could be discovered as the result of an MRI scan and cause emotional discomfort for the patient.

MRI Protocol Test and Optimization

Precautions

Projectiles

The following precautions will be used to prevent ferromagnetic objects from being introduced into the magnetic field and becoming projectiles.

1. All entrances to the 3T and 7T MRI console room will be controlled by magnetic-card readers. Only personnel trained in MRI safety will be allowed unrestricted access to the 3T and 7T MRI console room and scanner room. MRI safety training levels are defined below.
2. All personnel including research subjects, scanner operators, and investigators will remove all metallic objects before entering the MRI scanner room.
3. Research subjects will be under supervision of MRI safety trained personnel while in the 3T and 7T MRI console room and scanner room.
4. Research subjects will change into AU MRI Research Center supplied clothing (surgical scrubs) and will be scanned with a hand-held ferromagnetic detector before entering the MRI scanner room.
5. All portable objects entering the MRI scanner room will be clearly labeled as either MR Safe or MR Conditional.

Torsion and Translation Forces

To prevent implanted ferrous objects causing tearing or other injury to surrounding tissue, subjects with pacemakers, implanted cardioverter defibrillators, implanted metal in the head (for example aneurysm clips, but not including dental work), prior injury to the eye involving a metal object or fragment, any implanted medical device that electrically, magnetically, or mechanically controlled or activated, or any implanted or non-removable device or object that is not positively identified and known to be compatible with 3T and 7T MRI will not be scanned.

Vestibular Effect

To prevent a sensation of vertigo and nausea caused by vestibular effects, subjects will be instructed to lie down on the scanner table and rise from the scanner table slowly.

Peripheral Nerve Stimulation

This project will only use FDA-approved, Siemens WIP, or C2P imaging protocols, which will operate at dB/dt levels below those considered to be a significant risk according to FDA guidelines.

Acoustic Noise

Research subjects will be instructed to wear either AU MRI Research Center supplied earplugs or earphones specifically designed for the MRI environment.

Induced Currents and Electrical Interference

To prevent induced currents or with implanted devices or objects, subjects with pacemakers, implanted cardioverter defibrillators, implanted metal in the head (for example aneurysm clips, but not including

dental work), prior injury to the eye involving a metal object or fragment, any implanted medical device that electrically, magnetically, or mechanically controlled or activated, or any implanted or non-removable device or object that is not positively identified and known to be compatible with 3T and 7T MRI will not be scanned.

Radiofrequency Heating

The FDA sets clear guidelines for the amount of warming allowed during a scan (measuring the Specific Absorption Rate or SAR), and the scanner will not allow the operator to exceed these limits for FDA-approved, Siemens WIP, or C2P imaging protocols. Only FDA-approved, Siemens WIP, or C2P imaging protocols will be used in this project. The subject will be informed that if they have tattoos, there is some risk of burns, and that they should ask to stop the scan if any burning sensation is felt. Ice packs or cold compresses may be prospectively placed on any tattoos before the scan if it is practical to do so.

Suffocation

To prevent failure of the helium ventilation system, the ventilation system will be inspected on regular intervals. Also, the doors in both scanner rooms open from the scanner room into the console room, so the door can be opened even if there is positive pressure inside the scanner room. The scanner room is equipped with an oxygen sensor, which will sound an alarm if the oxygen in the air drops below a safe level. If the oxygen sensor alarm sounds, the building will be evacuated until told to reenter by the AU MRI Research Center staff. Emergency procedures in the event of a quench, including the possibility of a ventilation system failure, are described in Appendix D.

Heating of Tattoos

Participants with tattoos containing metal fragments or ink with iron oxide or other metals will not be scanned. The participant will be informed that if they have tattoos, there is some risk of warming at the site of the tattoo, and that they should ask to stop the scan if any heating sensation is felt. If a participant reports a heating sensation near the site of the tattoo during a scan, the scan will be stopped and the participant will be removed from the scanner and removed from the study.

Claustrophobia

Participants known to be claustrophic will be excluded from the study. If a participant becomes claustrophic during a scan, they can request that the scan be stopped either verbally or squeezing a ball given to them prior to being inserted into the scanner bore. The operator will immediately stop the scan and remove the participant from the scanner.

Nausea

If a participant become nauseous during a scan, they can request that the scan be stopped either verbally or squeezing a ball given to them prior to being inserted into the scanner bore. The operator will immediately stop the scan and remove the participant from the scanner. The operator will maintain visual and auditory (through a microphone in the scanner bore) contact with the participant at all times during a scan. If vomiting is observed, the operator will immediately stop the scan and remove the participant from the scanner.

Allergic Reaction to Adhesive ECG Patches

Participants will be asked if they have ever had an allergic reaction to an adhesive patch applied to their skin. If the participant has had an allergic reaction, the patches will not be applied.

Emotional Discomfort

If an abnormality is noticed in a scan, a standard diagnostic scan will be performed (if one has not already been performed) and referred to a radiologist for reading. If the radiologist determines that an abnormality does exist, the radiologist will contact the participant's personal physician, who will discuss the abnormal finding with the participant. If the participant does not have a personal physician, Dr. Kam at the Auburn University Medical Clinic will provide this service at the participant's expense. (see email below)

Appendix MRI 6: Emergency Procedures

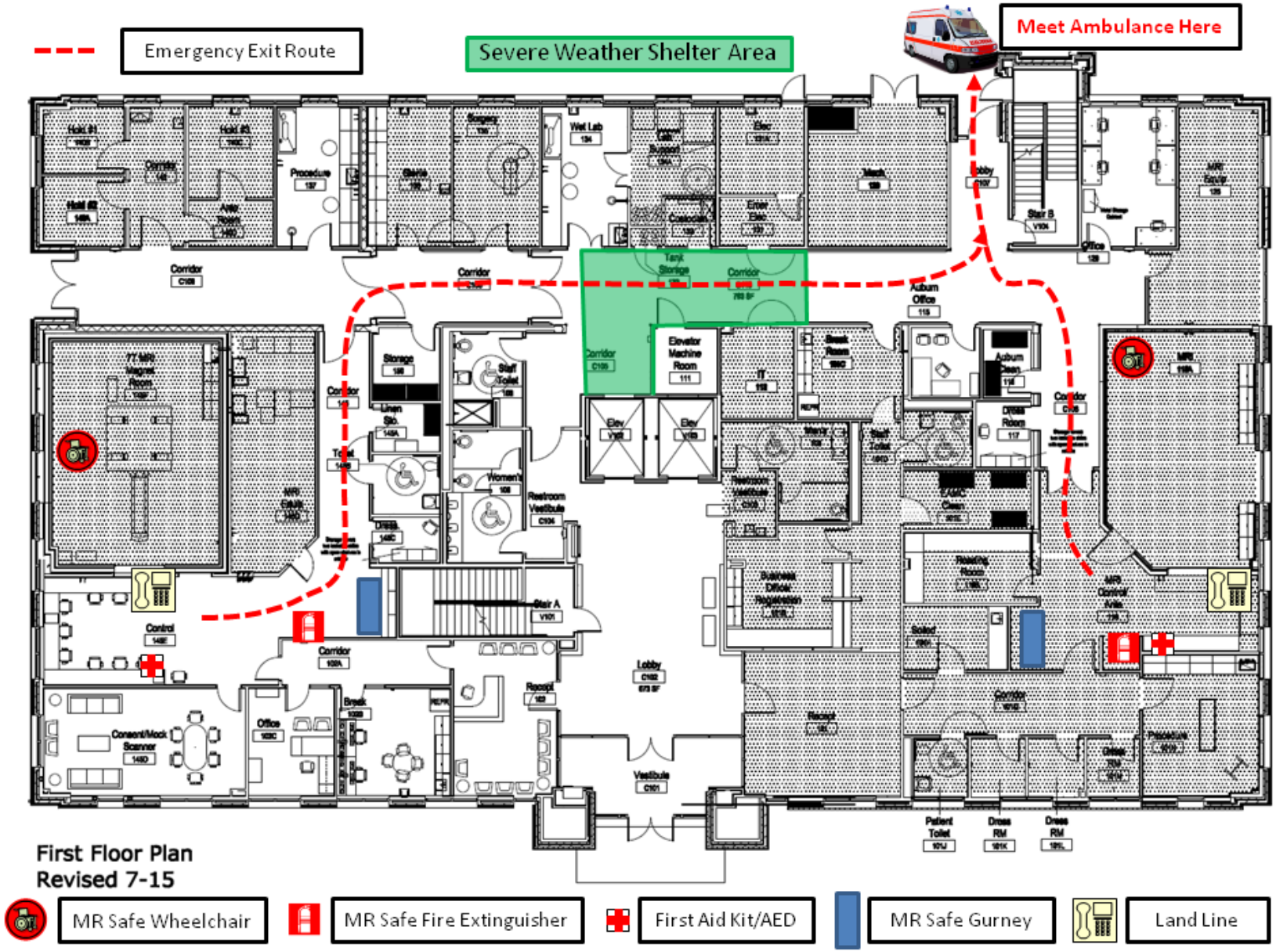
Emergency Contacts

	On-Campus	Off-Campus
In Case of Emergency	**9-911**	**911**
Ambulance	9-749-8504	(334) 749 8504
Non-Emergency: Auburn Police	9-501-3100	(334) 501-3100
AU MRI Research Center Main Office	4-6747	(334) 844-6747

Ron Beyers
MR Physicist and Safety Officer
Cell Phone: (334) 734-1566
Office Phone: (334) 844-7568
Home Phone: (334) 821-6309
rjb0018@auburn.edu

Tom Denney
AU MRI Research Center Director
Cell Phone: (334) 332-4639
Office Phone: (334) 844-1862
Home Phone: (334) 502-9603
dennets@auburn.edu

Julie Rodiek
AU MRI Research Center Administrator
Cell Phone: (334) 750-7286
Office Phone: (334) 844-7584
rodieja@auburn.edu


Emergency Exit Route
Severe Weather Shelter Area
Meet Ambulance Here
First Floor Plan
Revised 7-15
MR Safe Wheelchair
MR Safe Fire Extinguisher
First Aid Kit/AED
MR Safe Gurney
Land Line

Emergency Equipment

Emergency Electrical Power OFF (EPO) Button

1. Removes ALL system electrical power from the MRI console, patient table, and computers
2. Turns off the entire MRI system EXCEPT the static magnetic field and the emergency quench device
3. **DOES NOT produce a Magnet Quench**
4. Press this button ONLY to
    A. STOP A SCAN DURING A SUBJECT EMERGENCY
    B. STOP A SCAN DURING A SERIOUS EQUIPMENT FAULT OR HAZARD
        i. For example, an equipment FIRE

Emergency Magnet Quench Button

1. Rapidly reduces the magnetic field in approximately two minutes
2. WILL PRODUCE A MAGNET QUENCH and DEACTIVATE the MRI Magnet
3. **DOES NOT remove system Electrical Power**
4. UNLESS HUMAN LIFE IS AT STAKE, only the AU MRI Research Center Safety Officer or Director are authorized to activate the Emergency Quench Button.
    a. For example:
        i. If someone is pinned to the magnet
        ii. To remove a large ferromagnetic object from the magnetic field to prevent imminent injury to a subject.
5. Do NOT quench the magnet if an object is lodged in the scanner bore
    a. These objects can be safely removed by a Siemens service engineer
6. If applicable, follow the Quench Emergency Procedure (see page 47).

Emergency Access Door Release Button

1. Releases the pneumatic air pressure that secures the Access Door leading into the MRI Scanner room.
2. **DOES NOT remove system Electrical Power or produce a Magnet Quench**

These Emergency Response Buttons are redundantly located within both the MRI Console/Control Room (Figure 1) and the MRI Scanner Room (Figure 2).

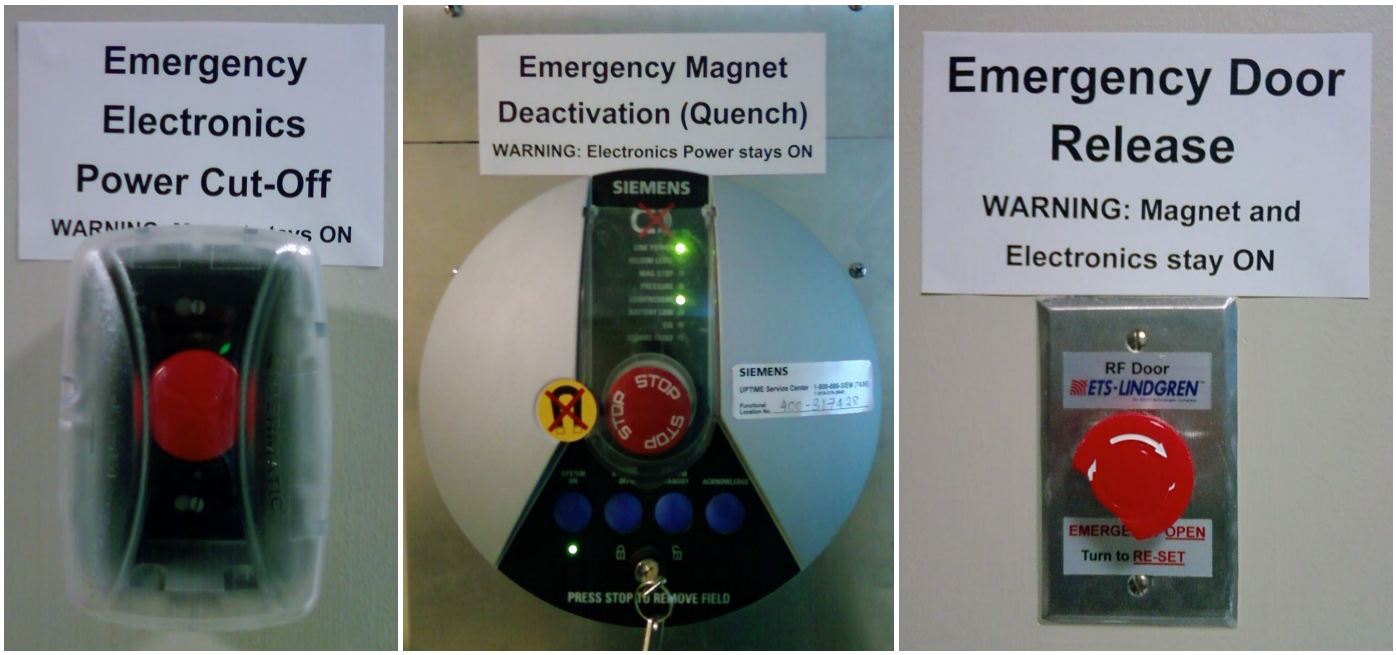


Figure 1a. Emergency Response Buttons inside the **3T Console/Control** Room

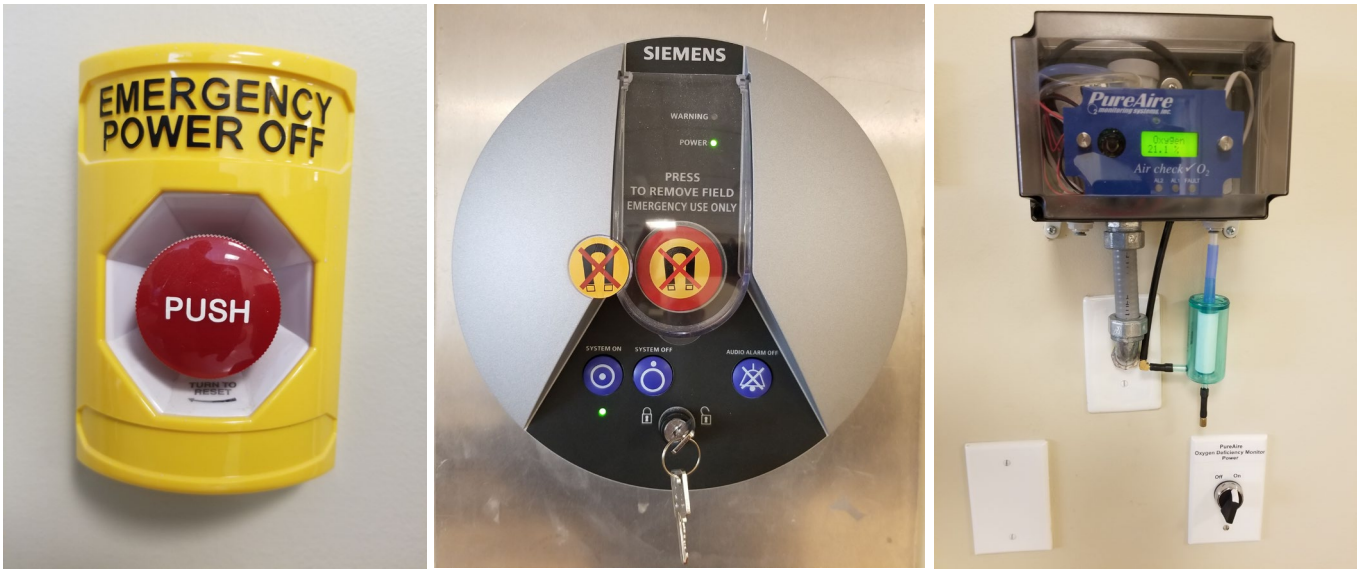


Figure 1b. Emergency Response Buttons inside the **7T Console/Control** Room

Figure 2a. Emergency Response Buttons inside the **3T Magnet/Scanner** Room

Figure 2b. Emergency Response Buttons inside the **7T Magnet/Scanner** Room

Oxygen (O2) Sensor Procedure

1. The O2 Sensor should be Powered ON whenever a person is inside the 7T Magnet room
2. In the event that the O2 Sensor Alarm sounds:
    a. Turn OFF the O2 Sensor Alarm Switch, but leave the Power Switch ON
    b. IMMEDIATELY REMOVE ALL PEOPLE from the 7T Magnet room
        i. Use CAUTION entering the 7T Magnet room that may have Helium present
        ii. Pull the Patient Table Drive Release Handle and Manually Pull the Table out
        iii. Remove Animals only if there is no risk to personnel entering the 7T Magnet room
        iv. Only ONE person should enter the 7T Magnet room while others stay in the Console room
    c. IMMEDIATELY BEGIN CPR on anyone UNCONSCIOUS from Helium Inhalation and CALL 911
    d. Read and Record the O2 Percentage Level displayed on the O2 Sensor
        i. Determine if the Alarm was Actual or False
    e. Contact Ron Beyers to report the incident
        i. Ofc: 334-844-7568, Mob: 334-734-1566, RJB0018@Auburn.edu

Medical Emergency Procedure

1. Remove the subject from the scanner bore and onto the MR Safe gurney if needed.
2. Do NOT perform emergency procedures in the scanner room.
3. Do NOT bring medical equipment into the scanner room.
4. Move the subject outside the scanner room.
5. Close the scanner room door to prevent entry of metallic objects.
6. Perform emergency CPR and first aid – if qualified to do so.
7. **Call 911** or EMS (*Lee County EMS is 749-8504*) and provide the following information
    a. Who you are
    b. General information about the injury or situation
    c. Where you are
        i. AU MRI Research Center Building
        ii. Auburn Research Park
        iii. Street address is 560 Devall Drive
        iv. 3T: 118 AU MRI Research Center
            1. Come in the back entrance to the MRI Center building.
            2. Turn left then right and go through the double doors.
        v. 7T: 145E AU MRI Research Center
            1. Come in the back entrance to the MRI Center building
            2. Turn right
            3. Go through two sets of double doors and enter the first door on your left.
    d. Any additional information
    e. BE THE LAST TO HANG UP!
8. Meet the ambulance at the street (Devall Drive) at the entrance to the gated parking lot and direct them to the back entrance to the MRI Center building.
9. Direct emergency personnel to the site you described in the phone call
10. If directed, assist emergency personnel with care of the injured person
11. Report the event immediately via telephone to the AU MRI Research Center Safety Officer
12. Report the event in writing to
    a. The principal investigator of the project
    b. AU MRI Research Center Director
    c. IRB via the Office of Human Subjects Research

Fire Emergency Procedure

1. Immediately remove the research subject from the scanner room and building.
2. Close all doors to contain the fire
3. **Call 911** and provide the following information
    a. Who you are
    b. General information about the fire
    c. Where you are
        i. AU MRI Research Center Building
        i. Auburn Research Park (Street address is 560 Devall Drive)
        ii. 3T: 118 AU MRI Research Center
            1. Come in the back entrance to the MRI Center building.
            2. Turn left then right and go through the double doors.
        iii. 7T: 145E AU MRI Research Center
            1. Come in the back entrance to the MRI Center building
            2. Turn right
            3. Go through two sets of double doors and enter the first door on your left.
    d. Any additional information
    e. BE THE LAST TO HANG UP!
4. If the fire occurs in the magnet room, the fire shall be extinguished using the non-ferrous fire extinguisher in the console room.
5. Notify the AU MRI Research Center Safety Officer immediately.

Magnet Quench Emergency Procedure

1. Use the intercom to tell the subject to stay calm and remain on the table.
    a. Tell the subject that someone will be in shortly to offer assistance.
2. All personnel in the console room not involved in removing the subject should exit the scanner room immediately.
3. Prop open the doors between the console room and the hallway to promote air circulation.
4. Open and prop open the scanner room door.
    a. If helium is venting inside the room, the scanner room door may fly open due to overpressure.
    b. Be aware of this possibility when opening the scanner room door to avoid injuries caused by unexpected opening of the door.
5. Enter the magnet room and help the subject exit the scanner room.
    a. Use the MR Safe gurney if needed.
    b. Be aware that helium fills the room from the ceiling down, so personnel standing upright are at greater risk than a subject lying in the scanner bore.
6. Evacuate all personnel from the MRI suite until the air is restored to normal.
7. Notify the AU MRI Research Center Safety Officer immediately.

Power Failure during an MRI Scan Procedure

1. Manually remove the subject from the scanner bore by pulling out the scanner table.
2. Escort the subject out of the scanner room.
    a. Remain with the subject until they have left the MRI suite or power is restored and scanning continues.
3. The scanner operator must return to the scanner console and shut down all computers in the console room that are running on uninterruptible power supplies (UPS).

Impending Severe Weather Event

DEFINITIONS

WATCH: Conditions are favorable for the development of severe weather in the Auburn area. Everyone should closely monitor the situation in case it gets worse.
WARNING: Severe weather has actually been observed, and there is an imminent threat to the Auburn area. Listen closely to instructions provided by weather radios/emergency officials.

THUNDERSTORMS

Frequently have high winds, cloud-to-ground lightning, heavy rain, and tornados.

LIGHTNING

1. Terminate any MRI scans in progress and remove the subject from the scanner room.
2. Evacuate the MRI scanner room and console room.
3. Stay away from telephones, electrical appliances, and plumbing.
4. If you can hear thunder, you are close enough to the storm to be struck.
5. Go to a safe shelter immediately.

IN THE EVENT OF SEVERE WEATHER

1. If you hear the weather siren or radio alerts,
    a. Terminate any MRI scans in progress
    b. Remove the subject from the scanner room
    c. Take shelter immediately in designated shelter location (1st floor hallway behind elevators).
    d. If people are in the first floor main lobby, open the door next to the elevators and direct them into the designated shelter location.
2. Sirens mean that there is a TORNADO WARNING, and you should seek shelter immediately.
3. If shelter is not available, move to the center and lowest point of your building.
4. Stay away from windows and doors to prevent injury from glass or other flying objects.
5. Cover your head with any heavy/bulky object to protect yourself.
6. Do not go outdoors to see the storm. Trained storm spotters will be monitoring the situation.
7. If flood water rises, do not attempt to wade or travel through the stream. Even small amounts of water can be very dangerous.
8. Report any injury/damage to the 911 dispatcher. Provide them as much information as possible to respond to the emergency.
9. Once the storm has cleared, notify Public Safety & Security/Emergency Management at (334) 844-8888 of any damages or injuries.

MRI Safety Training Levels and Qualifications for Scanner Operation

Definitions

- Level 1 training or higher is required for unrestricted access to the 3T and 7T MRI console room and scanner room.
- Level 2 training or higher is required to screen subjects and admit them into the MRI scanner room.
- Level 3 training is required to operate the 3T and 7T scanner.

Qualifications

- Level 1
    - Passed minimal safety educational efforts to ensure their safety as they work in the 3T and 7T MRI console room and scanner room.
    - Attend MRI Safety Seminar
    - Sign Level 1 MR Safety Form (attached).
- Level 2
    - Passed more extensive training and education on the broader aspects of MR safety issues.
    - Attend MRI Safety Seminar
    - Documentation of the following current certifications in safety of human subjects
        - CITI Human Subjects Research certificate
    - Sign Level 2 MR safety form (attached).
- Level 3
    - Passed Level 2 training
    - Current ARRT (American Registry of Radiologic Technologists) certification OR the following:
        - Documentation of Auburn University graduate student, staff, or faculty status
        - Documentation of the following current certifications in safety of human subjects
            - CITI Human Subjects Research certificate
            - Certification of American Heart Association basic life support at the health care provider level or equivalent
        - Observe Level 3 operators for at least three imaging sessions involving human subjects
            - Can be waived with approval of AU MRI Center Safety Director if completed Siemens Basic or Advanced Operator course.
            - Only one session is needed if completed similar operator course by another MRI scanner vendor.
        - Set up and perform at least three imaging sessions with human subjects under the supervision of a Level 3 operator.
            - Can be waived with approval of AU MRI Center Safety Director if completed Siemens Basic or Advanced Operator course.
            - Only one session is needed if completed similar operator course by another MRI scanner vendor.

        - The three observation scans and three supervised scans can be waived with a letter from the scanner vendor (Siemens Corp.) certifying the ability to operate the scanner.
        - Complete a solo check-out scan under the observation of a representative of the AU MRI Research Center and an ARRT technologist with Magnetic Resonance Imaging Certification.
        - Fill out the Level 3 (Scanner Operator) Approval Checklist (attached) and file with the AU MRI Research Center Administrative office.
    - Additional considerations for operating the 7T scanner
        - Level 3 operators will perform additional scans on the 3T scanner before operating the 7T scanner.
        - Scans in the 7T scanner can last up to 90 minutes, and participants have a greater chance of becoming nervous or apprehensive during a scan. Prior to operating the 7T scanner, Level 3 operators will receive additional training on the importance of communicating with the participant between scans and how to detect signs of apprehensiveness or nervousness in participants.

Auburn University MRI Research Center

Level 1 MRI Safety Training Form

I, _____, certify that I have completed and understood the material presented in the following MRI safety training (check one):

- ☐ MRI Safety Seminar Presenter:_____ Date:_____
- ☐ CE Essentials Web-based MRI Safety Training
- ☐ Other _____

I attest that the following has been accomplished as a part of the training:

1. I understand that the MRI scanners in the Auburn University MRI Research Center are ALWAYS ON – even when scanning is not taking place or when power is out – and that dangers associated with high magnetic fields are ALWAYS PRESENT.

2. I am aware of the dangers and risks associated with high magnetic fields and that certain items, both worn and implanted, should never be allowed in the 3T and 7T scanner rooms.

3. I am aware that only objects clearly labeled as MR Safe or MR Conditional can be brought into the 3T or 7T scanner rooms – even in case of an emergency.

4. I understand that all metallic objects or object possibly containing metal should be removed before entering the 3T or 7T scanner rooms including the following:

Watch / jewelry	Hearing aid
Keys / coins	Removable dentures
Hair pins / barrettes	Wigs
Piercings	Keys
Glasses	Credit cards
Safety pins	Metal buttons
Pens	Belt
Paper clips	Shoes with metal shank / toecap

By signing this document, I acknowledge my willingness to adhere to and fulfill the safety recommendations and guidelines conveyed in this training.

*Signature*_____ *Date* _____

Department/Organization _____

*Phone #*_____ *E-mail* _____

Auburn University MRI Research Center

Level 2 MRI Safety Training Form

I, _____, certify that I have completed and understood the material presented in the following MRI safety training:

- ☐ MRI Safety Seminar Presenter: _____ Date: _____
- ☐ Collaborative Institutional Training Initiative (CITI) Expires: _____
- ☐ CITI Responsible Conduct of Research (RCR) Expires: _____
- ☐ Review of AUMRIRC Safety Manual Date: _____

I attest that the following has been accomplished as a part of the training:

1. I understand that the MRI scanners in the Auburn University MRI Research Center are ALWAYS ON – even when scanning is not taking place or when power is out – and that dangers associated with high magnetic fields are ALWAYS PRESENT.
2. I am aware of the dangers and risks associated with high magnetic fields and that certain items, both worn and implanted, should never be allowed in the 3T and 7T scanner rooms.
3. I am aware that only objects clearly labeled as MR Safe or MR Conditional can be brought into the 3T or 7T scanner rooms – even in case of an emergency.
4. I have been instructed in appropriate procedures for screening individuals who will enter the 3T and 7T scanner rooms, such that their safety will not be compromised by introduction of inappropriate items into the high magnetic field environment.
5. I am aware of the risks associated with the acoustic noise associated with MRI acquisitions, and made aware of procedures for mitigating the associated effects.
6. I have been instructed in appropriate emergency procedures associated with conducting MRI studies, either on humans or animals.

By signing this document, I acknowledge my willingness to adhere to and fulfill the recommendations and guidelines of the Auburn University MRI Research Center, as conveyed in this training and in the Auburn University MRI Research Center Safety Program.

*Trainee Signature*_____ *Date* _____

Department/Organization _____

*Phone #*_____ *E-mail* _____

*Confirmation Interviewer (printed name):*_____

Confirmation Signature (or initials) _____ *Date*_____

Auburn University MRI Research Center

Level 3 (Scanner Operator) Approval Checklist

Personal Information:

Name _____

Department_____

Position _____

E-mail _____

Phone _____

Verified Certification Dates (copies on file):

CPR Training _____ (*Valid Until:*_____)

MRI Safety Seminar _____ (*Valid Until:* _____)

CITI Human Subjects Training _____ (*Valid Until:* _____)

CITI RCR Training _____ (*Valid Until:* _____)

☐ Letter from scanner vendor on file certifying ability to operate the scanner (check here)

Observe at least three (3) imaging sessions involving human subjects:

1. Primary Operator _____ Date _____
   Experiment equipment used: _____
2. Primary Operator _____ Date _____
   Experiment equipment used: _____
3. Primary Operator _____ Date _____
   Experiment equipment used: _____

Conduct at least three (3) imaging sessions involving human subjects, supervised by a Level 3 operator:

1. Supervising Operator _____ Date _____
   Experiment equipment used: _____
2. Supervising Operator _____ Date _____
   Experiment equipment used: _____

****

Pre-Checkout AUMRIRC Evaluator (printed name) _____

3. Supervising Operator _____ Date _____
   Experiment equipment used: _____

Final Checkout (solo operation supervised by AUMRIRC representative):

AUMRIRC Rep _____ _____
Signature Date Printed Name

Procedure for Incidental Findings

1. During the screening process, the participant is given the option of providing the name and contact information for their primary care physician on the Pre-Entry Screening Form.
2. If an abnormality is noticed in a scan, a standard diagnostic scan will be performed (if one has not already been performed) and referred to a radiologist for reading.
3. If the radiologist determines that an abnormality does exist, the radiologist will contact the participant's primary care physician (if name and contact information is provided on the Pre-Entry Screening Form), who will discuss the abnormal finding with the participant.
4. If the participant does not have a primary care physician or does not list a name and contact on the Pre-Entry Screening Form, Fred Kam, M.D. at the Auburn University Medical Clinic will provide this service at the participant's expense. (See attached email from Dr. Kam).

From: Fred Kam
To: Thomas Denney
Date: Tuesday, June 11, 2024 at 4:57:23 PM Central Daylight Time
Subject: Re: Incidental Findings in MRI Research Scans

Hi Tom,

I am willing to continue serving as a clinician along with my team to follow up any abnormality on the research MRI for those participants who do not have a primary care clinician .

Most sincerely,
Frederick Kam MD

From: Tom Denney <dennets@auburn.edu>

Sent: Tuesday, June 11, 2024 4:42 PM

To: Fred Kam <kamfred@auburn.edu>

Subject: Incidental Findings in MRI Research Scans

Dr. Kam,

The IRB has requested an updated email from you stating that you, or one of the other physicians at the AU Medical Clinic, will
follow up the abnormality on a research MRI for any participant who does not have a primary care physician and for whom we
receive a radiologist report. Their contact information will be provided to you and the AU Medical Clinic will initiate the contact for an
appointment at the participant's cost.
If you are still willing to provide this service, can you send me an email to that effect?

Regards,
Tom
--
Thomas S. Denney Jr., Ph.D.
Mr. & Mrs Bruce Donnellan & Family Endowed Professor,
Department of Electrical and Computer Engineering
Director, AU MRI Research Center
Co-Director, Alabama Advanced Imaging Consortium
Auburn University
560 Devall Drive, Suite 202
Auburn, AL 36849-5551
(334) 844-1862

MRISAC 7T MRI Implant Policy

Background

MRI scanners have three magnetic fields that interact with participant implants in different ways. The interaction of all three of these fields on an implant must be considered.

Static magnetic field: The static magnetic field (e.g. 1.5 Tesla (T), 3T, 7T) is always on and only affects ferrous metals (metals that are attracted to a magnet). Implants that contain ferrous metal components are MRI Unsafe and patients with implants containing ferrous metals are not imaged for research purposes at the AU MRI Research Center.

Magnetic field gradients: Magnetic field gradient coils generate linear spatial changes in the static magnetic field. Gradient coils in 7T MRI scanners are the same as those in 1.5T and 3T scanners and have mild effect on implants. The gradient coils generate magnetic fields that are substantially weaker than the static magnetic field, so their effect on ferrous metal implants is substantially weaker than the effect of the static magnetic field. Importantly for gradient effects, since gradients are the same at 1.5T, 3T and 7T fields, any implant already documented as MRI Conditional at lower fields (1.5T and 3T) is MRI Conditional for 7T (for gradient effects).

RF field: The RF field is a time-varying magnetic and electric fields generated by a transmit coil inside the scanner bore. The RF field operates at in a frequency range that is dependent on the static magnetic field. The frequency range is around 64MHz for a 1.5T scanner, 128MHz for a 3T scanner, and 300 MHz for a 7T scanner. The RF electric field causes slight heating of the body during an MRI scan. The amount of temperature rise is difficult to predict for a specific MRI pulse sequence, so, instead, the Food and Drug Administration (FDA) regulates the heating based on specific absorption rate (SAR) as power per unit body mass (Watts/kg). Importantly, all MRI scanners have locked internal safeguards that ensure the SAR for any MRI pulse sequence is within FDA limits. Generally, SAR is not a concern for implants.

However, at 7T with the shorter the RF field wavelength (6), localized heating in and around certain implants containing non-ferrous metal may occur and must be avoided. The size and location of an implant determine the heating by the transmit RF field. At 7T, an implant with a size greater than 14 cm can match the RF field wavelength to cause the “antenna effect” and induce heating. This is why the MRI community accepts dental implants at 7T because of their small size. Implant manufacturers test their devices for RF heating and classify them into three categories: MRI Safe, MRI Conditional, and MRI Unsafe. MRI Safe means that the implant contains no metallic components and participants with these implants can be imaged at any field strength. MRI Unsafe implants contain ferrous metal, can be irreparably damaged by an MRI scan, or otherwise are incompatible with MRI. All other implants are considered MRI Conditional.

In lower field strength scanners (3T or less), the transmit RF field is normally applied by a full-body-sized coil that is built into the scanner bore. This transmits an RF field that covers most of

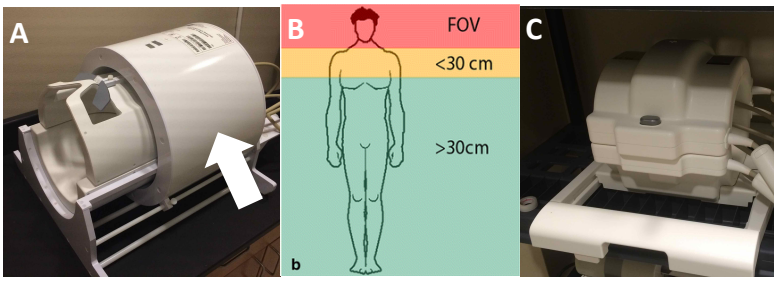


Figure 1. A. The 7T head transmit/receive coil (Nova Medical, USA), at the AU MRI Research Center. The transmit coil is the cylindrical object at the top of the coil (white arrow). The transmit coil slides over the top of the head during a head MRI scan. B. Location of implants relative to the head coil for head scans. The red area represents the body region exposed to the head coil transmit field. The yellow area represents the body region less than 30cm from the head coil. The green area represents the body region greater than 30cm from the head coil. Adapted from Noureddine, et al (5). C. The 7T knee transmit/receive coil (QED, Inc, USA) at the AU MRI Research Center.

the body that is inside the scanner bore. 7T scanners do not have a body coil and the RF field is transmitted by a smaller coil that is fit to the body part being imaged. The transmit coil is combined with a receive coil, (which passively receives the RF signal from the body) either in the same assembly (Figure 1A) or in the same housing (Figure 1C). For example, in the head coil shown in Figure 1A, the transmit coil is the cylindrical outer coil and the receive coil is the inner coil with eye holes. Figure 1C shows a transmit-receive knee coil. Both the transmit coil and receive coil is built into the coil housing. Importantly for all transmit RF coils, the field strength in the body drops down rapidly with distance from the coil (2).

Current Policy

The MRI Center's current policy is to not image at 7T any participant with a metallic implant of any type except for dental work (fillings, retainers, crowns, etc.). Participants with dental work are allowed to be imaged at 7T by a policy change previously approved by the MRISAC. Participants with non-metallic implants have always been imaged at 7T at the MRI Center.

New Policy

Participants with non-ferrous, but metallic implants may be imaged at 7T if the following conditions are met. These conditions are based on recommendations from the German Ultra-high Field Imaging (GUFI) group (4) and Noureddine et al 2015 (5).

1) The implant is located more than 30cm away from the transmit coil (Figure 1B).

2) The implant's largest dimension is less than 14cm. Implant documentation, if available, will be used to determine the largest dimension of the implant. If implant documentation is not available, the participant will self-report what the implant is. If the implant is clearly 14cm or less (for example, an ankle screw), it will be allowed. If the implant is of unknown size, or is clearly 14cm or longer, then it will be disallowed.

3) The implant is MR Conditional at 3T or MR Safe.

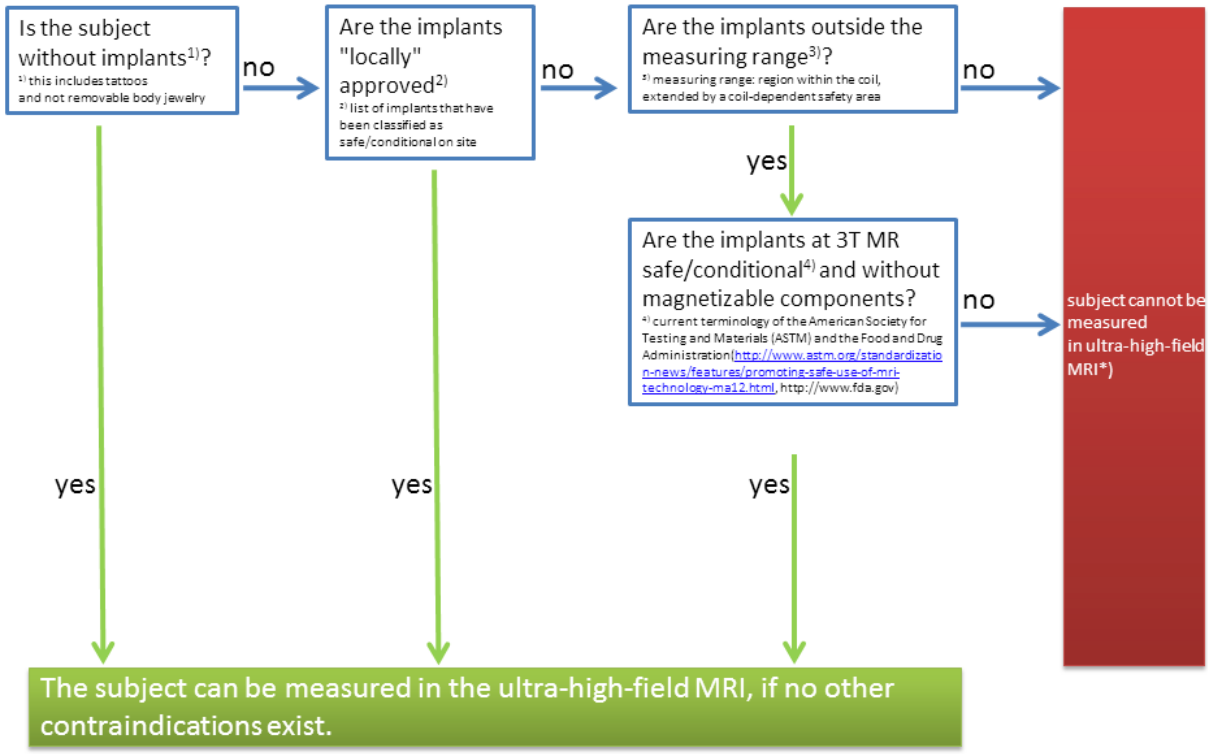
4) The implant is not programmable (e.g. defibrillators, pacemakers, deep brain stimulation devices)

5) The implant is not in the brain

Rationale

This policy change request is motivated by the following factors:

Approved by the AU MRI Safety Advisory Council March 23, 2023



*) If security is not determined by this flowchart, an examination can only be realized if a validated field simulation was performed for the specific passive implant and thereby can be shown that any limit values are kept.

Figure 2: Procedure for determining if a patient with an implant can be scanned at 7T recommended by GUFI (4).

Upgrade to 7T Terra / Need to Image Older Participants

In November of 2022, the AU MRI Research Center will upgrade its current 7T MRI scanner, which is not FDA certified for clinical use, to a state-of-the art Siemens Terra 7T MRI scanner, which will be FDA certified for clinical use. We anticipate that the ability of the Terra to perform clinical MRI scans to increase the number of clinical trials involving the MRI Research Center. Participants in clinical trials are typically older individuals that are more likely to have implants. The ability to safely image participants with implants will allow the MRI Research Center to participate in these trials.

7T MRI Uses Transmit/Receive Coils Instead of a Body Coil

As described above, 7T MRI scanners do not have a body coil. Instead, they use transmit/receive coils. The transmit RF field drops off rapidly outside a transmit/receive coil and the RF field will be too low to affect implants located far from the transmit coil (2). To avoid any possible “antenna effect” RF field coupling, implants with its largest dimension greater than 14 cm are excluded from imaging (1).

Recent Research on 7T MRI With Implants

Approved by the AU MRI Safety Advisory Council March 23, 2023

Recent research has shown that, under conditions 1-3 above, 7T MRI is safe for patients with implants (2,5). Note that conditions 4-5 are additional restrictions. The German Ultra-high Field Imaging (GUFI) group published position papers (4) with recommendations on how to approve implants for 7T imaging, which are summarized in Figure 2. Noureddine et al (5) reported a study of 230 patients imaged at 7T with implants >30cm away (Figure 1A) from a head coil that is the same model as the one used in the AU MRI Research Center (Nova Medical, Boston, Massachusetts). In this study, "None of the subjects reported sensations of heat or force before, during, or after the examination. None expressed any discomfort related to implants/tattoos."

References

1. Brunner DO, De Zanche N, Fröhlich J, Paska J, Pruessmann KP. Travelling-wave nuclear magnetic resonance. Nature. 2009 Feb 19;457(7232):994-8. doi: 10.1038/nature07752. PMID: 19225521. **Traveling wave effect**

2. Dula AN, Virostko J, Shellock FG. Assessment of MRI issues at 7 T for 28 implants and other objects. AJR Am J Roentgenol. 2014 Feb;202(2):401-5. doi: 10.2214/AJR.13.10777. PMID: 24450683. **"Because the 7-T MR system currently does not have a transmit radiofrequency body coil, MRI related heating and artifacts are not a concern for metallic objects present outside the head."**

3. Fagan AJ, Bitz AK, Björkman-Burtscher IM, Collins CM, Kimbrell V, Raaijmakers AJE; ISMRM Safety Committee. 7T MR Safety. J Magn Reson Imaging. 2021 Feb;53(2):333-346. doi: 10.1002/jmri.27319. Epub 2020 Aug 24. PMID: 32830900; PMCID: PMC8170917. **References GUFI and Noureddine paper.**

4. https://mr-gufi.de/images/documents/Approval_of_subjects_for_measurements_at_UHF.pdf. Accessed August 23, 2023.

5. Noureddine Y, Bitz AK, Ladd ME, Thürling M, Ladd SC, Schaefers G, Kraff O. Experience with magnetic resonance imaging of human subjects with passive implants and tattoos at 7 T: a retrospective study. MAGMA. 2015 Dec;28(6):577-90. doi: 10.1007/s10334-015-0499-y. Epub 2015 Sep 26. PMID: 26410044. **Tested implants 30cm away from the head coil**

6. Ilka Dove, "Analysis of Radio Propagation Inside the Human Body for in-Body Localization Purposes", M.Sc. Thesis, University of Twente, August 2014 **Background to determine 7T wavelength inside the human body.**

Approved by the AU MRI Safety Advisory Council March 23, 2023