CENTER FOR FUNCTIONAL AND MOLECULAR IMAGING

GEORGETOWN UNIVERSITY MEDICAL CENTER

Standard Operating Procedures Manual

1. Intro to Center

The Center for Functional and Molecular Imaging at Georgetown University Medical Center consists of faculty, research assistants, post-doctoral fellows, and graduate students with expertise in structural, functional and molecular brain imaging. We combine brain imaging with behavioral methods to explore the neural mechanisms of thought, feeling, movement and perception and to explore the mechanisms underlying the acquisition and functioning of cognitive and sensorimotor skills.

With a particular focus on developmental neuroimaging, we study children and adults with a range of developmental disorders, including developmental dyslexia, autism, and attention-deficit disorder. For most of our studies, we also include healthy children and adults as controls. Understanding the brain mechanisms responsible for learning will provide important new information about the biological roots of the different learning styles seen in these individuals. Our ultimate goal is to utilize recent advances in brain imaging and behavioral analysis in the service of developing improved tools for diagnosis and treatment.

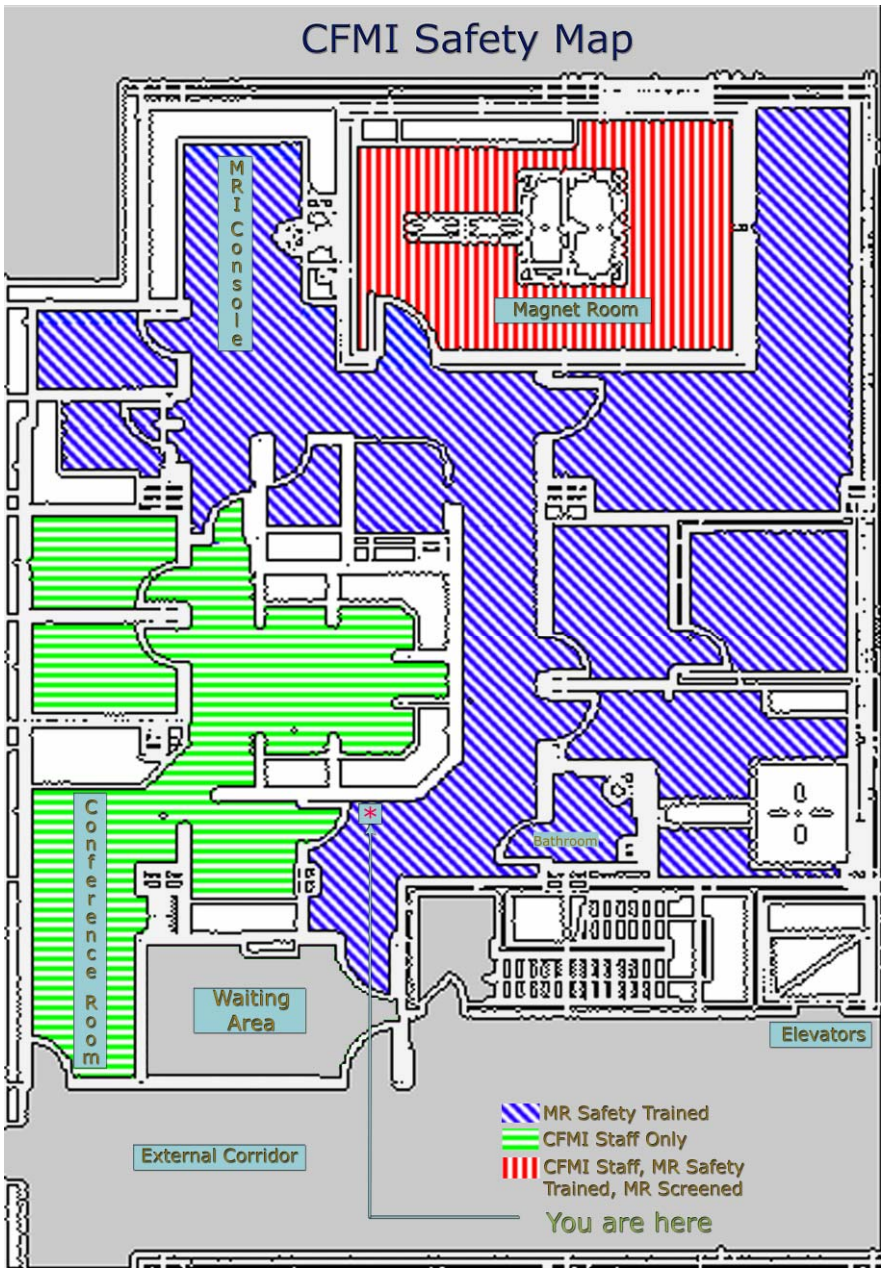
In addition, we are involved in a series of Security and Intelligence Studies including an experiment designed to uncover the neural signatures of deception, a spatial rotation training study designed to investigate the development of satellite imagery skills, etc.

The Center for Functional and Molecular Imaging is supported by the National Institutes of Health (NIH), the National Geospatial Intelligence Agency (NGA), and Defense Advanced Research Projects Agency (DARPA).

2. Center Information

2.1 Map of CFMI OF User Accessibility

This map is sectioned off by areas open to CFMI staff only, MR safety trained individuals, and those who have been MR screened. This map DOES NOT designate the safety zones.
All non-safety trained individuals (e.g. participants, visitors, facilities personnel, etc.) should be accompanied by a safety trained individual at all times during their visit at the center.



2.2 Zones

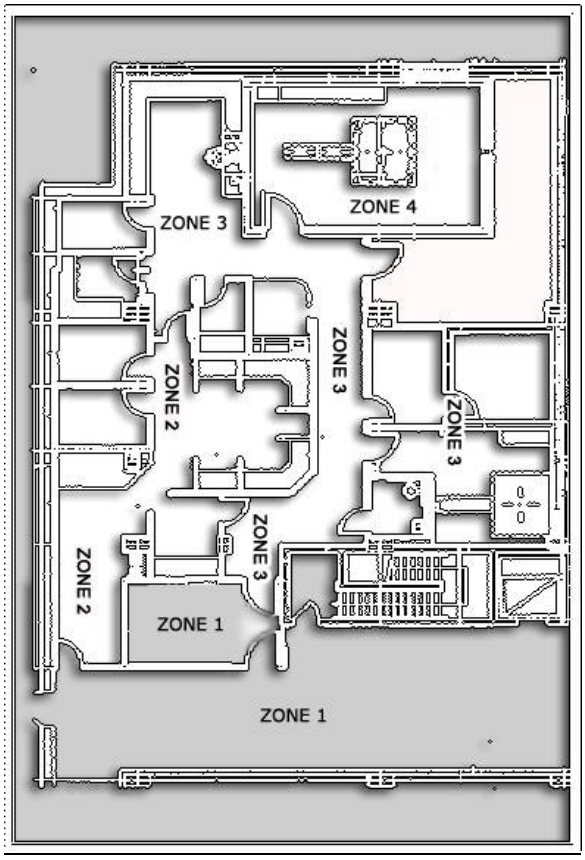
The center is divided up into zones based on the American College of Radiology White Paper on MR safety. (AJR:178, June 2002 1335-74).

ZONE 1= Area outside MR environment, accessible to the general public

ZONE 2= Interface area between publicly accessible uncontrolled Zone I and the strictly controlled Zone III & Zone IV

ZONE 3= Restricted from public access, accessible only to personnel that have completed MR Safety Training; non-trained personnel must be accompanied at all times

ZONE 4= Synonymous with the scanner room itself, accessible only to those that have completed MR Safety Training and adequately completed the MR screening form



2.3 Phone List

Contact List	**202-68(7)-**
Emergency	**7-4357 (7-HELP)**
MRI Console	7-0110
Reception Desk	7-3592
Preclinical Sciences Bldg LM-14 Conference Table	7-7383
Bldg D-177 Conference Table	7-1130
Mock Scanner	7-5092
Fax Number	7-7906
Authorized User	7-4871

Name	E-mail @georgetown.edu	202-68(7)-
Banke Adeyemo	aaa63	7-3963
Sujeeta Bhatt	sbb2	7-4966
Bridget Creney	bcc7	7-4161
Larry Fields	fieldsl	7-6167
Katie Fitzpatrick	kef29	7-3592
Stan Fricke	stf2	7-4628, 7-4802
Anna Germain	aeg26	7-0655
Aviel Ginzburg	apg6	7-1130
Andrea Gropman	ag334	7-3625
Ayichew Hailu	ah322	7-4076
Mark Happel	mdh35	7-1125
Jana Kainerstorfer	jmk84	7-3592
Leah Lozier	lml46	7-2107
Jessica Matz	jmm274	7-8794
Juma Mbwana	jsm53	7-3865
Andrei Medvedev	am236	7-5126
Tysie Sawyer	ats23	7-1129
Kyle Shattuck	ks355	7-3592
John VanMeter	jwv5	7-8767
Tom Zeffiro	taz	7-6776

Medical Center Facilities	E-mail	202-68(7)-
Craig Day	dayc	7-3995
Clinton Edwards (daytime housekeeping mgr)	cce6	7-4424
Leonard Henery (nighttime housekeeping mgr)	heneryl	7-2134
Work Management	(light bulb change etc.)	7-3432

Updated: January 31, 2006

3. Rules for working/ using CFMI

3.1 Training (see also Training section)

PIs' are responsible for ensuring all employees and staff working on MRI projects are trained through the Safety Training Course in order to access the facility. In addition, it is mandatory that each individual who will be accessing the facility must complete a screening questionnaire to ensure their safety.

3.2 PI Responsibilities

1. You will conduct your study strictly according by the IRB. As the principle investigator you will be accountable for your own research and the protection of human studies. You will ensure, at all times, that you have the appropriate resources

and facilities to conduct this study. You will ensure that all research personnel involved in the conduct of the study have been appropriately trained on the protection of human subjects, in addition to the study procedures.
2. Any adverse or serious adverse event MUST be reported to the IRB according to IRB policy as well as to the authorized user in CFMI.
3. Any changes/additions/revisions to your research plan must be submitted to the IRB for review and approval prior to implementation. This includes changes or additions requested by the sponsor.
4. Your protocol MUST be reviewed annually by submission of the appropriate application to the IRB. Failure to submit renewal documents to the OHRP by the administrative due date indicated on the renewal notice may result in termination of the study by the IRB.
5. Advertisements for the recruitment of subjects must be approved by the IRB prior to implementation.

3.3 Console room

3.3.1 Before entering the console room:

A. Make certain the research participant is registered in the CFMI participant registration system.
B. Before entering the console room you must have provided the scanner operator with completed & signed consent and screening forms, including the ID that will be used for that participant when starting the session on the console computer. Ensure that you have made any necessary photocopies of documents so that the consent and screening forms provided to the scanner operator at this time are the CFMI copy.
C. The investigator group must limit themselves to three people before entering the console room.
D. Only those individuals that have been through CFMI's safety training may enter this area unless *prior* permission is obtained from the CFMI Authorized User.
E. There will be NO behavioral testing in CFMI unless prior permission is given by the Facility Manager or Center Director.

3.3.2 During the scanning session:

A. There will be absolutely NO food or drink allowed in the console room.
B. One parent may accompany the child that is involved in a pediatric study. Siblings are not allowed in the console room except to view their sibling briefly and then they must return to the waiting area.
C. No strollers or other large, potentially dangerous metallic items may be taken into the console room.
D. When in the console room, please limit your talking to the necessary communication for the scanning to proceed safely in the allotted time frame.
E. The investigator group must initiate the scanning session on the logging computer as soon as they enter the console area.
F. No behavioral data should be copied from the stimulus presentation computer in the console room.
G. The door between the office area and console room should remain closed at all times, only CFMI staff may enter this area.
H. At no time will a group of investigators be allowed in the console area while another group is scanning.

3.3.3 Scanning session is completed

A. Remove any items that your group brought with them into the console area.
B. End the session on the logging computer only when the participant has been taken out of the scanner and the console/magnet room is ready for the next group.
C. Exit the console area immediately after the area is clean and the participant has returned to the waiting area.

3.4 Conference / Waiting room / Common area

A. No food or beverage debris is to be left in the conference or waiting area. It is the responsibility of the PI, **NOT** CFMI, to clean up after their participants after they have left the facility. Those who do not clean up after themselves or participants may lose food/beverage privilege for the conference and waiting areas.
B. Any materials left over from a lecture, meeting or participants are to be removed at the end.
C. Items (Pens, pencils, etc.) left in the rooms are the responsibility of the owner as we do not currently have a lost and found.
D. Chairs are not to be "borrowed" from the Center.

3.5 CFMI Onsite Recruiting Policy

In order to maintain participant confidentiality and compliance with IRB policy CFMI has outlined the following rules regarding recruitment at the center. These guidelines are also intended to minimize any conflict of interest that might arise due to recruiting efforts on the center premises, as well as provide an unbiased access to resources available.

3.5.1 Flyers

Any IRB approved flyers that include imaging will be allowed in the waiting room only and will be available to any members of the public who enter this facility

3.5.2 Verbal Inquiries

All staff, when directly asked from a participant or a parent of a participant, who is not directly involved in that staff members research study, may direct them to pick up any of the flyers in the waiting room; NO further efforts to actively recruit, solicit, entice these participants are to be made.

3.5.3 Other

A. All staff members may recruit participants ONLY with IRB approved methods that are stated explicitly in IRB protocol.
B. All staff members must complete HIPPA and Subject Safety Training annually and file these documents with the appropriate offices.

3.5.4 Staff Initiated Recruitment

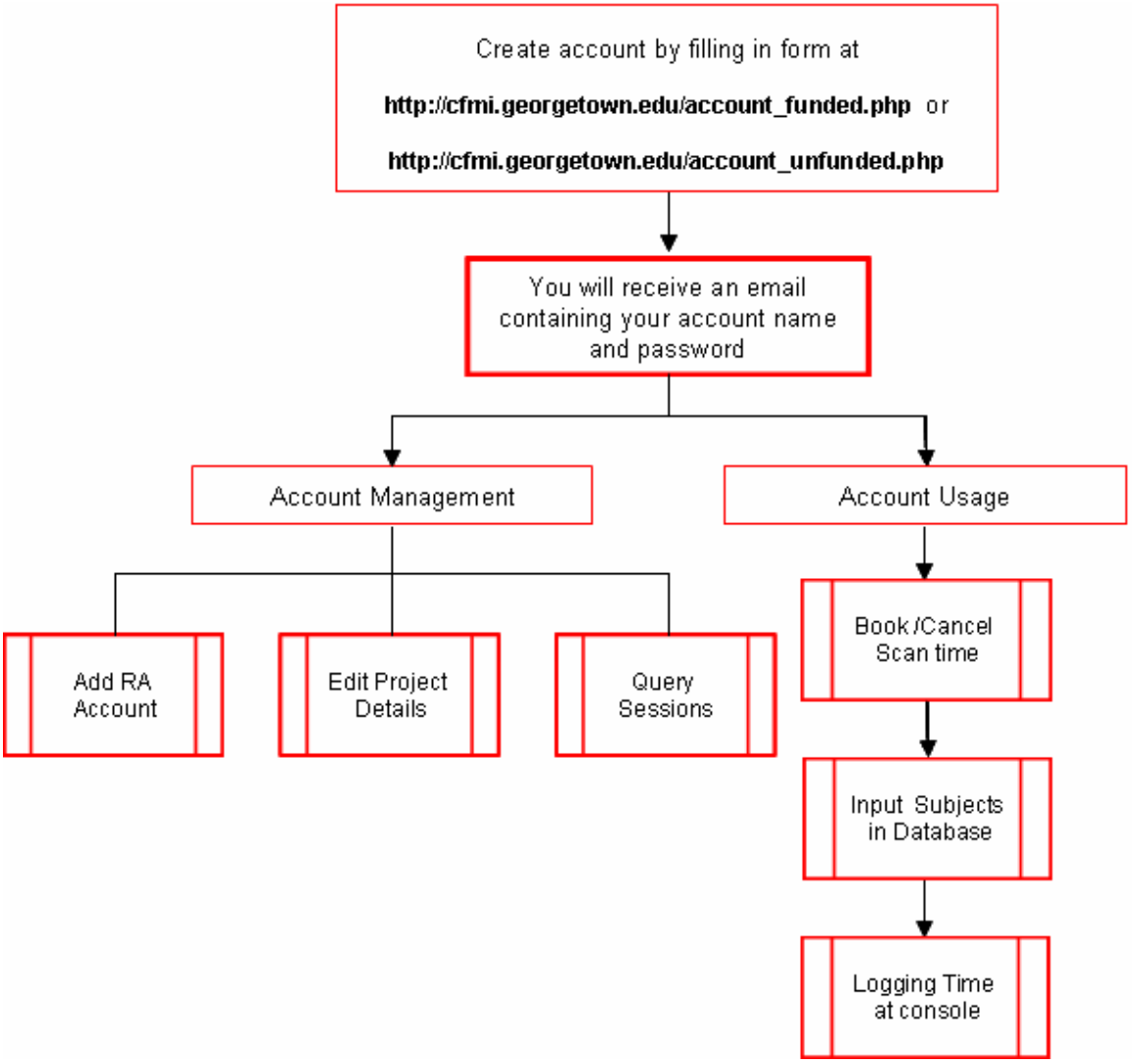
A. Under no circumstances can staff members engage with a subject participating in another lab's study for the purpose of recruiting that subject.

B. Under no circumstances can personal information volunteered by a subject participating in another lab's study such as those provided on the MRI Safety Screening form and the logging system be used for the purpose of recruiting subjects.

3.6 CFMI New Scan Logging System

This section is designed to assist in using the new Logging System that has been implemented at CFMI. The new logbook will assist in the automation of the billing process to improve accuracy and speed. In addition, it will allow each researcher to look at a scanning session's information, such as changes in sequence of runs, aborted scans, breaks, and other pertinent information the operator entered during the scan. Please note that the CFMI scanning policies before the implementation of this new system still apply. If you have any questions or concerns regarding this system please send them to mri_time@cfmi.georgetown.edu. You can also drop by our lab and ask one of our Research Assistants for a quick demo. Thank you for your cooperation.

3.6.1 Flow Chart



3.7 Step-by-Step Procedure

3.7.1 Getting a Funded Account

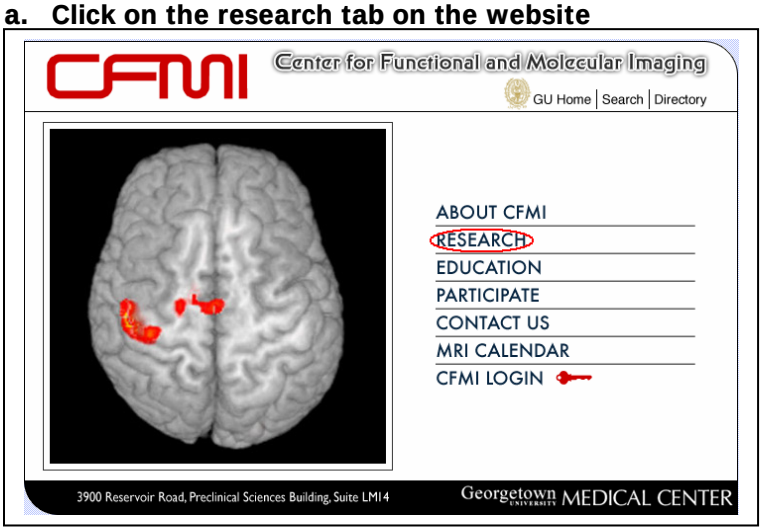
1. To obtain a user account for a new/existing project for which you have funding, visit **http://cfmi.georgetown.edu/account_funded.php** (You will be required to supply a fund number and billing information.) For an approved unfunded study visit **http://cfmi.georgetown.edu/account_unfunded.php**

2. You will be provided with a user name and password. With which you can sign on to your account.

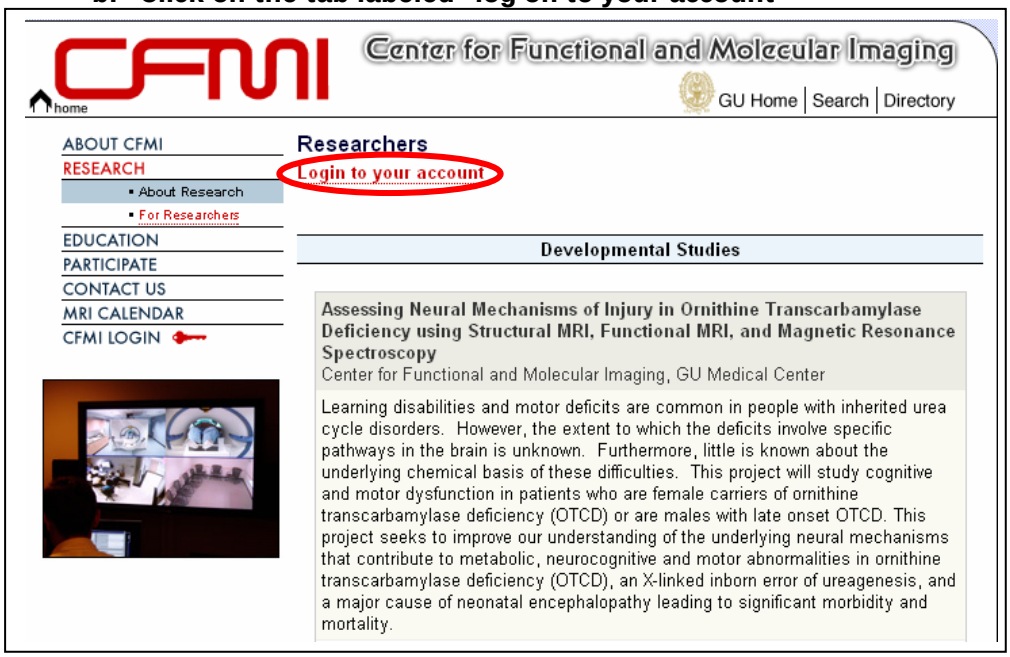
3.7.2 Account Management

Editing Project details

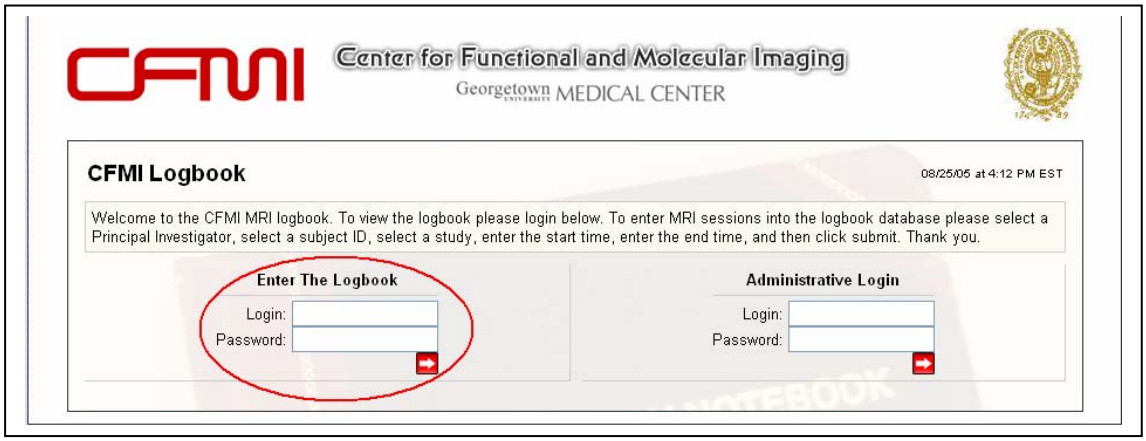
a. Click on the research tab on the website



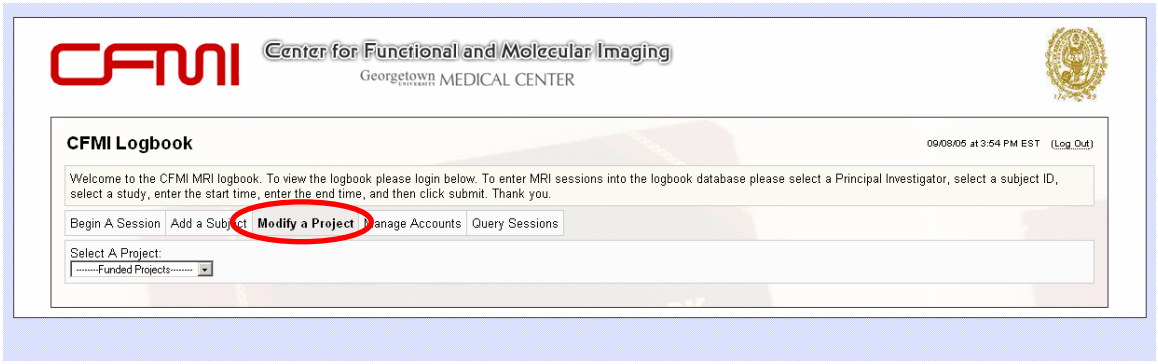
b. Click on the tab labeled "log on to your account"



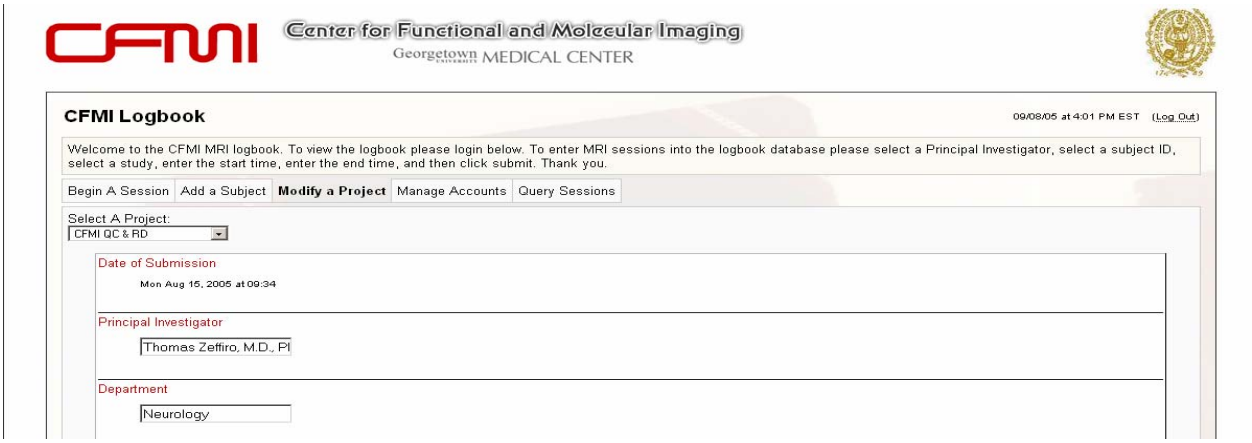
c. Log on with your account name and password



d. Click on the tab labeled Modify a Project

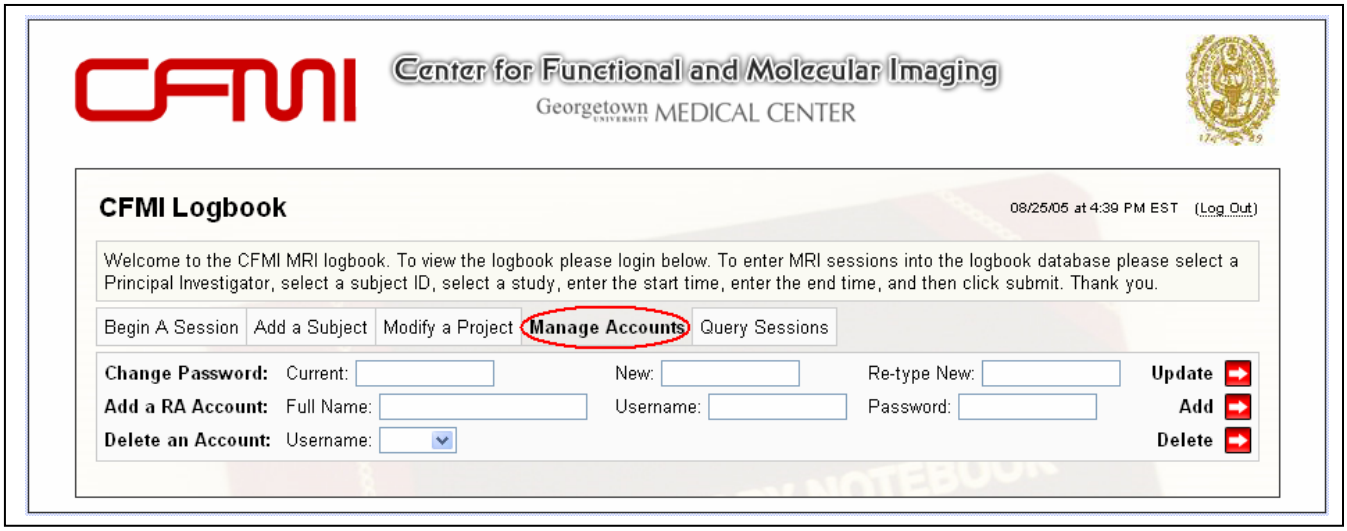


e. Select the project you wish to edit and edit necessary fields



Add RA Accounts

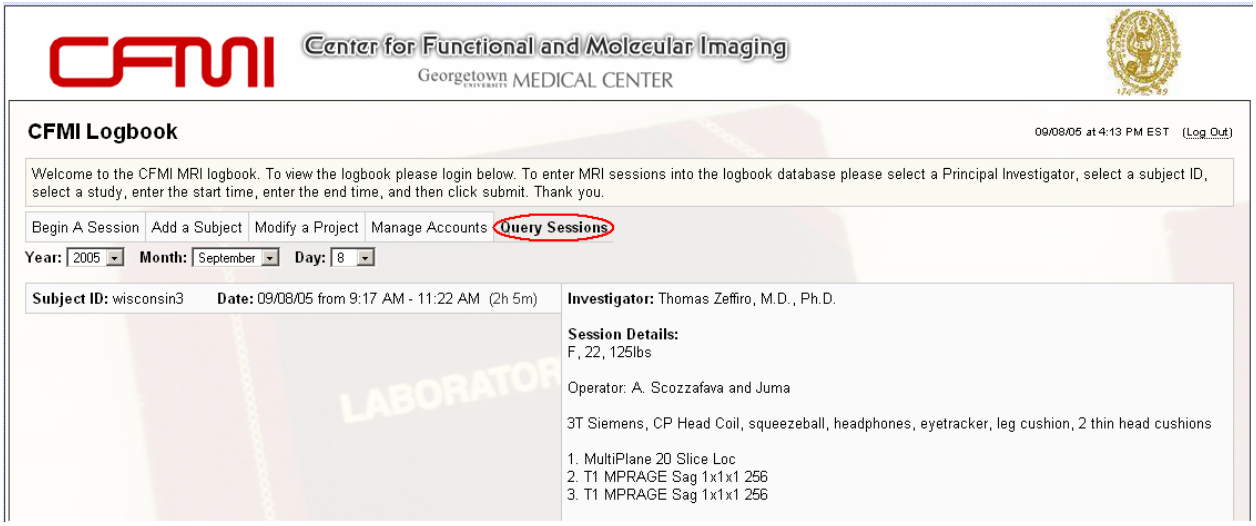
a. Click on the tab labeled "Manage Accounts"



b. Fill out user information then click on the add button

Query Sessions

a. Click on the tab labeled "Query Session"
b. You can view details of past sessions by choosing the relevant dates from the menu

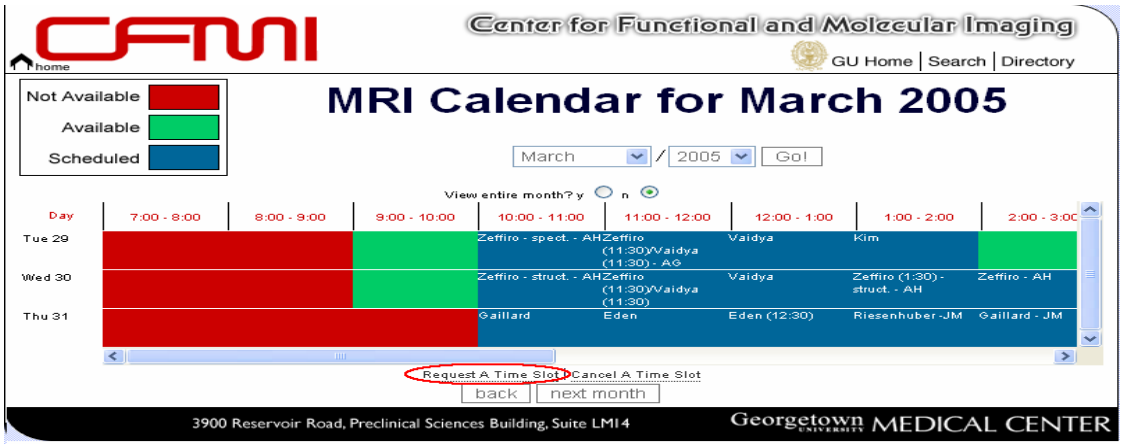


3.7.3. Account Usage

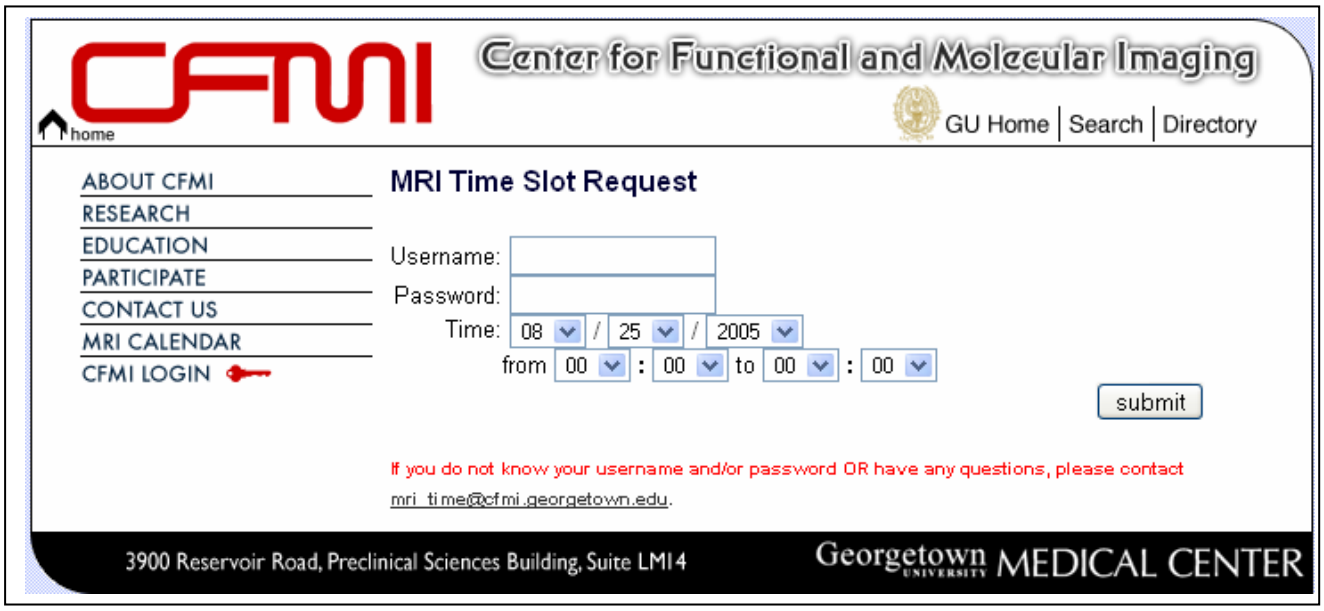
Request a Time slot

After you set up your RA's accounts they can start booking time on the MRI calendar at http://cfmi.georgetown.edu/calendar.php

1. Request a time slot
   a. Select Request a time slot



b. Enter username and password

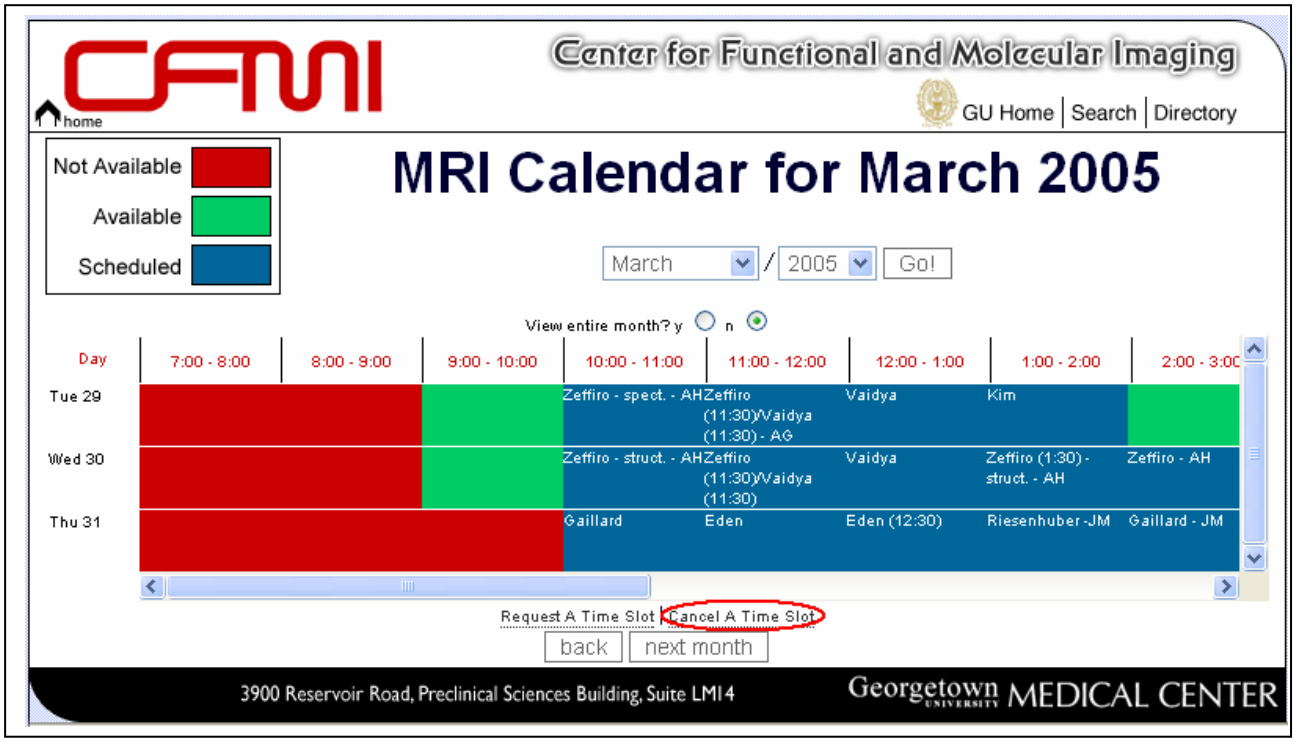


c. Select Date and Time being requested. Be sure to account for the time needed for the setup and wrapping up after a scan.

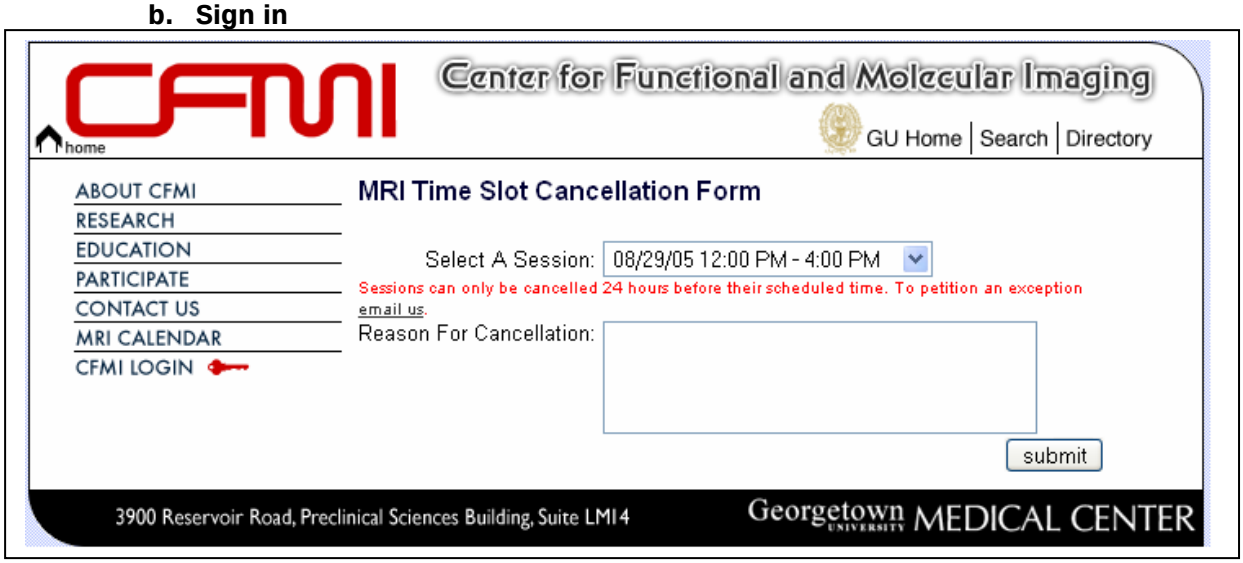
d. Click Submit button.

2. To Cancel a session go to http://cfmi.georgetown.edu/calendar.php

a. Select Cancel a time slot



b. Sign in



c. Select scheduled session
d. Enter Reason for Cancellation
e. If Cancellation is within 24 hours of requested time slot please email mri_time@georgetown.edu

Regular CFMI scheduling rules are still in effect. For emergency booking or cancellation send an email to mri_time@cfmi.georgetown.edu

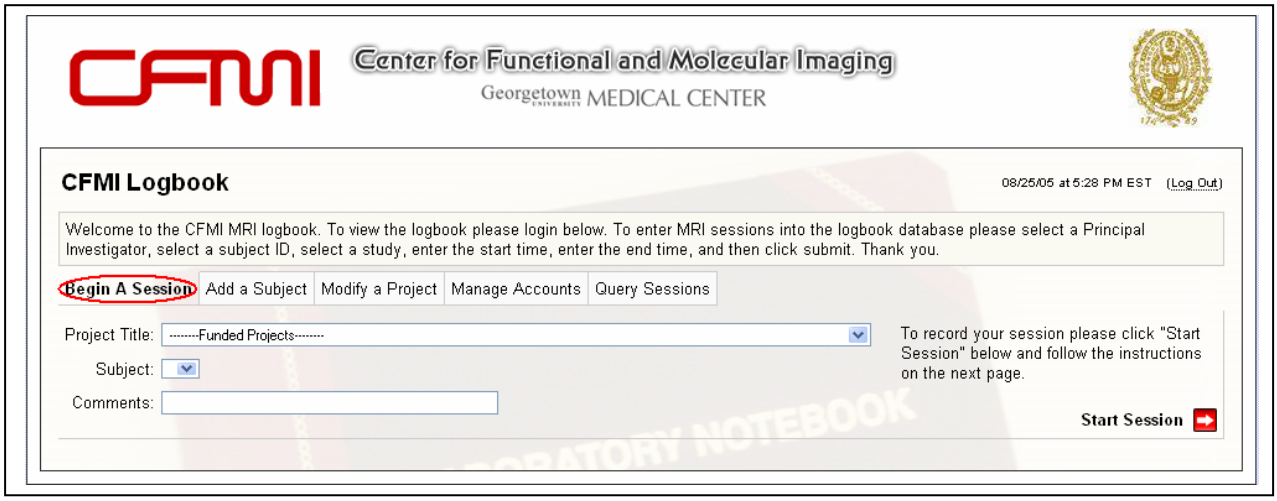
3. It is important that Users enter their subject data into the database **BEFORE** coming to the lab for a scan.
   a. Go to the Add a Subject tab

b. Fill out subject information

c. Click add button

4. After a subject has been added to the database, the User may sign on to the logbook and begin a scan session.

a. Select your study from the list.



b. Select your subject from the list.
c. Select scheduled session
d. Click start session

5. **At the end of the scan do not forget to log off. YOUR ACCOUNT WILL BE CHARGED FROM INITIATION OF SCAN TILL YOU LOG OFF.**

4. Project Proposals

Visit the CFMI website (http://cfmi.georgetown.edu) to fill out a project request.

4.1 Grant Submissions/ forms (see web-site for additional info/forms)

New Funded Projects
New research using the CFMI core facilities may be initiated with a research proposal. Research proposal forms can be located on the CFMI website. New projects may be funded, or the goal of the project may be to collect pilot data for a grant application.

Application approval is dependent on the following:
- Scientific merit
- Feasibility of the research on existing equipment
- Availability of equipment
- Budget review and ability of the investigator to support the user fees

PI's on approved proposals will receive email notification and further instructions.

All research involving human subjects to be conducted at the Center for Functional and Molecular Imaging must be approved by the Georgetown University IRB. Check out the IRB web-site

(http://ora.georgetown.edu/irb/) for more information on obtaining IRB approval. If you have questions or would like help with your IRB application, contact the Georgetown University IRB Office (202) 687-6553.

All research involving animals at CFMI must first be approved by the GUACUC.

4.2 New Development Accounts (unfunded)

Development Accounts are available to investigators engaged in research for the development of CFMI hardware, software, and imaging techniques that will be of general use to the CFMI community.

4.3 IRB Compliance Requirements

Investigators performing human studies at the Center for Functional and Molecular Imaging must submit documentation of compliance with IRB regulations. We cannot assign scan time or allow use of the scanners without IRB documentation. This information will be kept in the investigator's file at CFMI and will be used by the CFMI staff to verify adherence to protocol. Please help us keep this information up to date.

The following documents must be submitted for each protocol:

- Most recent IRB approval letter for protocol
- Electronic copy of Detailed Protocol section from approved IRB application
- Number of subjects approved
- Names of persons other than PI or Co-Investigator who are authorized to obtain informed consent (include documentation of IRB approval)
- Copy of any amendments made to subject selection/enrollment (including requests to enroll additional subjects) or study procedures for IRB protocols, and amendment approval letter

4.4 Requirements

4.4.1 GU Requirements

When submitting a grant proposal for research involving the Center for Functional and Molecular Imaging, the Principal Investigator is responsible for addressing the specific requirements of the granting agency and their home institution. Additional requirements of CFMI are summarized below. General guidelines for submitting grant proposals for research at CFMI can be found on the Research and Technology Development Services web page (http://data.georgetown.edu/schmed/rtds/index.html).

4.4.2 CFMI Requirements

a. **Materials to Submit to the Center for Functional and Molecular Imaging**
The principal investigator of all grants that propose work at the Center for Functional and Molecular Imaging are required to:
   - Notify the Scientific Management Committee (CFMI Senior Administrator) one month prior to submission
   - Submit to the CFMI a copy of the entire grant at the time it is submitted

b. **Materials to obtain from the Center for Functional and Molecular Imaging**
The following documentation must be included in your grant proposal. These materials can be obtained through prior arrangement with the CFMI Center Office.
   - The CFMI Research Proposal Cover Sheet
   - Biosketches of CFMI researchers involved in the proposed project

- 'Other Support' document for CFMI researchers who will receive payment from proposed project
- Description of CFMI resources and environment Paragraph describing the CFMI cost structure for budget
- 'Sign-off' on in-house part of funding application
- Imaging Time Approval
- Budget Approval
- Conflicts of Interest Form

4.5 Sample Grant Application

A sample successful grant proposal is available for inspection at the Center for Functional and Molecular Imaging Office.

4.6 Billing/ funding / pilot time

All scanning time is billable. Pilot time is considered part of scanner time, so be sure to include that into your scanning budget. Time is billed for the time requested for scanning, NOT the time the subject enters the scan room, but the time you have reserved for scanning. If your scan time runs over the requested scan time, you will be billed to the next quarter hour.

5. Time Allocation

5.1 Scheduling MRI time procedures

5.1.1 Time Requests for the 3.0T MRI System

All requests for scanner time must be submitted through the online calendar. No other requests will be considered. This is being done to streamline and automate the scheduling process. Automated scheduling will allow us to allocate time slots more objectively and to re-do the scanner schedules more often. More frequent revisions of the schedule will allow researchers more flexibility in their scanning time as well as the ability to coordinate experiments with grant deadlines, visiting collaborators, etc.

If you have gotten this far, you should be able to complete and submit the time request form. If, however, you have trouble submitting the form electronically or have questions about the form itself, please contact one of us at CFMI. (mri_time@cfmi.georgetown.edu). Hours of Operation for 3T scanning

Monday, Tuesday, Thursday, and Friday: 9am – 6pm
Wednesday : 9am – 8pm
Saturday : 10am – 6pm

5.1.2 Scheduling policies:

1. MRI time requests must be submitted within 24 hours of the desired time slot in order to be considered. Special considerations will be taken into account for those submissions made less than 24 hours in advance.
2. An MRI time slot cancellation must be submitted within 24 hours prior to the designated time slot; otherwise, you will be billed for the requested time slot. Please note the reason for canceling a time slot, as this is looked at to see who is abusing the canceling policy (a group with frequent cancellations may face scanning penalties).

3. Three Saturdays a month will be available for scanning. Groups must request at least a 4 hour time block to make it worthwhile for the Authorized User to come in for that day. Once a 4 hour block has been reserved, additional hours may be requested by the same group or other groups within the available time for scheduling on a weekend. Only those Saturdays designated on the calendar with an Authorized User present are available for scheduling.

5.2 Mock Scanner Usage

All researchers who have requested MRI scanning time will have access to the Mock Scanner room 15 minutes prior to scan time in order to familiarize subjects with the MRI environment prior to the actual scan. For ALL other times, you MUST submit a request to use the Mock scanner room two (2) weeks prior to the desired date in order to ensure availability. **NO behavioral testing in or other activities are to be done on CFMI premises unless prior permission is given by the Facility Manager or Center Director.**

5.3 Requesting Independent Operator and Open Slots

Please visit our calendar to find an available time slot. E-mail your time request including the date, the time (A.M. or P.M.), which scanner and the PI to mri_time@cfmi.georgetown.edu. A confirmation e-mail will be returned notifying you that you have the time. **Please use e-mail only for requests (or cancellations).** Verbal requests are not accepted. This is to ensure that we have a record of your request and you have a record of the confirmation. -Please re-check the calendar to make sure that the slot was entered correctly.

5.4 Special Requests

We will make every attempt to accommodate special requests (e.g. requests for daytime scan hours with technical support). However, with the growing number of studies vying for magnet time, we ask that users consider their special requests carefully and try to be as flexible and as reasonable as possible.

5.5 Tours

ALL tours requests (including media interviews/photographs) must be submitted two weeks prior to the tour date to mri_time@cfmi.georgetown. In addition, John VanMeter must be notified. If there is a scan scheduled at the time of the tour which does not pertain to your study, it is up to you to check with the scheduled user to ensure that the tour will not interfere with the scheduled scan session. For all tours, a CFMI member MUST be available (not busy or scanning) to accompany the tour. Please avoid bringing tours through the office/cubicle area. All tours with children (under 18 years of age) MUST be accompanied at ALL times by a CFMI member. Only tours of five or less people are permitted to tour through the center at one time.

5.7 Use It or Lose It

Past utilization of assigned scan time will be taken into consideration each time the schedule is

re-made. Frequent non-use of scheduled scan time indicates a problem that should be discussed before additional time slots are allocated, and may result in a reduction of a user's assigned time in the next iteration of the schedule. After each scheduling period, the history of magnet use will be reviewed carefully for the purpose of improving efficiency.

5.8 Cancellation Procedures

Provided that you give at least 24-hours notice that you are unable to use your scheduled time slot, you will not be billed for that time. Submit your cancellations at http://cfmi.georgetown.edu/calendar.php and the appropriate changes will be made in the calendar. Please make sure to note the reason for the cancellation. If you do not give at least 24-hours notice and you do not show up for your time slot, you will be billed for the entire block of time reserved. You must still cancel the slot by emailing mri_time@cfmi.georgetown.edu.

The only exception is if a subject cancels at the last minute (or if there is some emergency). In this case, you must send an e-mail to mri_time@cfmi.georgetown.edu as soon as you know you will not be using the time slot (**please provide the reason for cancellation**). Please make every effort to keep these incidents to a minimum by calling subjects to confirm appointments and by making sure that subjects know when and where to report for the study, and how they can reach you at any time. It is our opinion that no-shows and last minute cancellations are rare, but if the records indicate that this is a problem for any particular group, special arrangements will be made.

DO NOT give up your time slot to another group if you are not going to use it. We are often looking for time for the pulse programmers or for time to pay back groups whose time slots we had to take for repairs or updates. If we do not need the time, the slot will be opened up on the calendar and then given to the first requester.

6. Training

6.1 Safety Training

Successful completion of the CFMI MRI Safety Training Course is required for all investigators working in the facility.
The program will include a 1-hr MRI safety lecture, viewing of an MRI safety video, tour of the magnet room, practice in subject screening and a brief exam.
Course materials are available on the CFMI website education section and should be read prior to attending the lecture.
Course Director: Tom Zeffiro, MD PhD and John VanMeter, PhD

6.2 MRI 3T Siemens Training

The purpose of this training is to educate the student in the basics of the operation of the MRI scanner. This training will include a combination of lectures and hands-on use of the scanner. Students who pass this training will be qualified to operate the scanner, provided:

a. The student has also successfully completed the MRI Safety Training Course (§ 6.1 Safety Training)
b. An authorized user is present in the MRI facility

c. The scanning session has been approved through the appropriate scheduling procedures

Students will be evaluated on the basis of multiple quizzes, demonstration of competence and other factors based on the instructors evaluation of each students seriousness and proper respect for the potential dangers involved with MRI. Completion of this training does not automatically entitle the student to operate the scanner.

Course Director: John VanMeter, Ph.D.

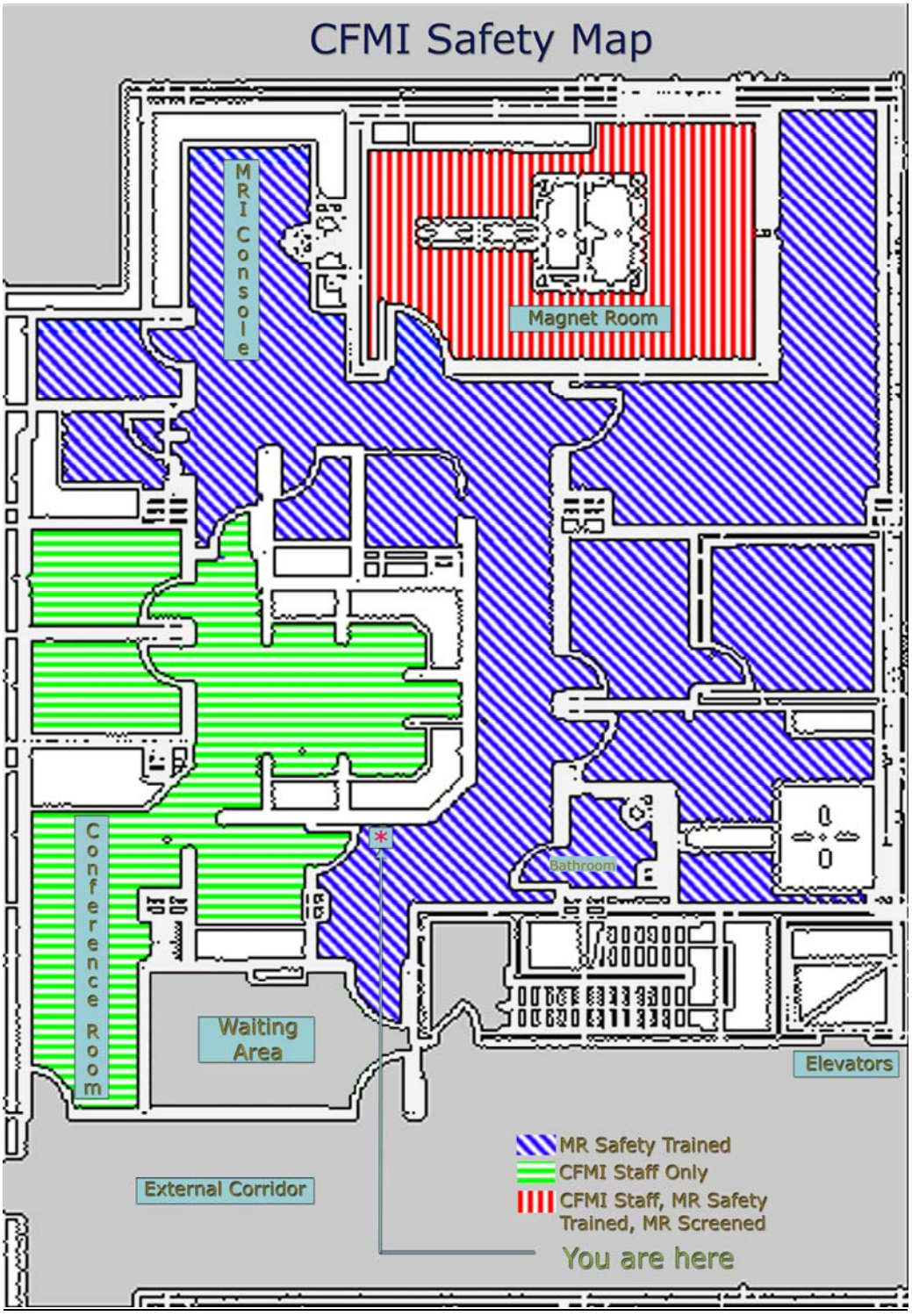
6.3 Image Analysis Training

The purpose of this training is to educate the student in the basic analysis of fMRI data. The emphasis will be on the techniques used in the Center. To find out more about when this training is given please visit the CFMI website education section of the center's website; course materials are available online to be read prior to attending the lectures.

Course Director: John VanMeter, Ph.D.

7. Safety

7.1 Zone map



7.2 Hazards/ dangers

Magnetic Resonance Imaging (including spectroscopy, conventional, and fast imaging techniques) have been in use for over a decade, and are viewed as medical procedures associated with acceptable and well controlled risks. However, technological advances in MRI (higher static fields, faster gradients, stronger RF transmitters) have occurred rapidly and many questions regarding the safety of these developments remain unanswered. This document provides an introduction to some of the safety concerns associated with MR research. Other related pages address the practical implications of these safety issues.

7.2.1 Static Magnetic Fields

a. Projectiles

The most immediate danger associated with the magnet environment is the attraction between the magnet and ferromagnetic objects. Ferromagnetic metal objects can become airborne projectiles when placed in a strong magnetic field. The strength of the field increases super linearly with the distance from the magnet bore, and even hand-held objects can be jerked free very suddenly as the holder moves closer to the magnet. (Small objects, such as paper clips and hairpins, have a terminal velocity of 40 mph when pulled into a 1.5T magnet.) In addition to the possibility of severely injuring someone, it is not good for the magnet to be bombarded with difficult to remove small metal items. Remember, even when you are not scanning, the magnet is ALWAYS “ON”.

NEVER bring any metal objects into the scanner rooms.

b. Metal in the Body

Metallic objects in the body can also have dangerous effects when placed in a magnetic field. Ferromagnetic metal implants or fragments may twist or move causing internal injury. Even non-ferromagnetic metal (including metal on clothing) can heat up during scanning, causing burns or discomfort. Many of our subject screening criteria are aimed at avoiding these hazards. In addition, metal in or near the body (such as dental implants) can produce artifacts which adversely effect image quality.

7.2.2 RF guidelines/ SAR

a. Tissue Heating

An RF pulse (a short burst of an electromagnetic wave originating from the RF coils) is used in MRI to "excite" tissue protons by an exchange of energy. This absorption of RF energy can potentially cause heating of the tissue. Absorption of RF power by the tissue is described in terms of Specific Absorption Rate (SAR), which is expressed in Watts/kg. (In the US, the recommended SAR level for head imaging is 3.2 Watts/kg.) SAR in MRI is a function of many variables including pulse sequence and coil parameters and the weight of the region exposed. However, the actual increase in tissue temperature caused by exposure to RF radiation is dependent on the subjects’ thermoregulatory system (e.g. tissue perfusion, etc.). The risk of exposing subjects with compromised thermoregulatory function (e.g. elderly patients and patients taking medications that affect thermoregulation, such as calcium-blockers, beta-blockers, diuretics, or vasodilators) to MR procedures that require high SAR levels has not been assessed.

b. Electrical Burns

RF fields can cause burns by producing electrical currents in conductive loops. When using equipment such as surface coils, ECG or EEG leads, the investigator must be extremely careful not to allow the wire or cable to form a conductive loop with itself or with the subject. Coupling of a transmitting coil to a receiver coil may also cause severe burns.

7.3 Quenching

Quenching refers to the events that occur when the liquid cryogens that cool the magnet coils boil off rapidly, which results in helium escaping very rapidly from the cryogen bath. This means that the coils cease to be superconducting and become resistive. A quench will in general be accompanied by a loud bang or thundering with the cold gas expulsion.

Quenching may occur by activation of the magnet STOP button, or spontaneously, caused by a fault in the magnet itself. The magnet emergency stop button should only be used in the event that the magnetic field may possibly causing patient or personnel injury, and a shutdown of the static field is necessary, or if fire or some other unforeseen occurrence requires the quick access of emergency personnel to the examination room. Note, however, that initiating a quench may not result in total removal of the magnetic field, and a danger may still exist.

In case of emergency contact the on site Authorized User and follow instructions provided by the Authorized User.

7.4 Noise

Vibrations of the gradient coil support structure of the MRI scanner create sound waves. These are caused by the interactions of the magnetic field created by pulses of the current through the gradient coil with the main magnetic field in a manner similar to a loudspeaker coil. The sounds made by the scanner vary in volume and tone with the type of procedure being performed. MRI system noise levels increase with field strength. It is required that ALL participants wear protective headphones during the scan session. Additional ear protection is available if necessary.

7.5 Other Concerns

7.5.1 Pregnancy

There are no known adverse effects of MRI on developing fetuses. Most early studies on pregnant animals were negative for teratogenic effects, and a recent survey found no association between working in the MR environment and a number of pregnancy outcome variables*. However, given the scarcity of data on the subject and the high susceptibility of the developing fetus to damage in general, we believe it is not worth the risk for pregnant women to participate as subjects in MR research studies. Most clinical units allow pregnant employees to enter the scan room, but not to remain in the room while the RF and gradient fields are applied during image acquisition. Pregnant researchers at CFMI are expected to regulate their own exposure to the magnets.

For additional and up-to-date information, see MRIsafety.com

*Shellock , FG & E Kanal , Magnetic Resonance: Bioeffects , Safety, and Patient Management, 2nd Edition, Lippincott -Raven, Philadelphia , 1996, pp. 342.

8. Scanning

8.1 Human studies

8.1.1 Forms – screening, consent, etc

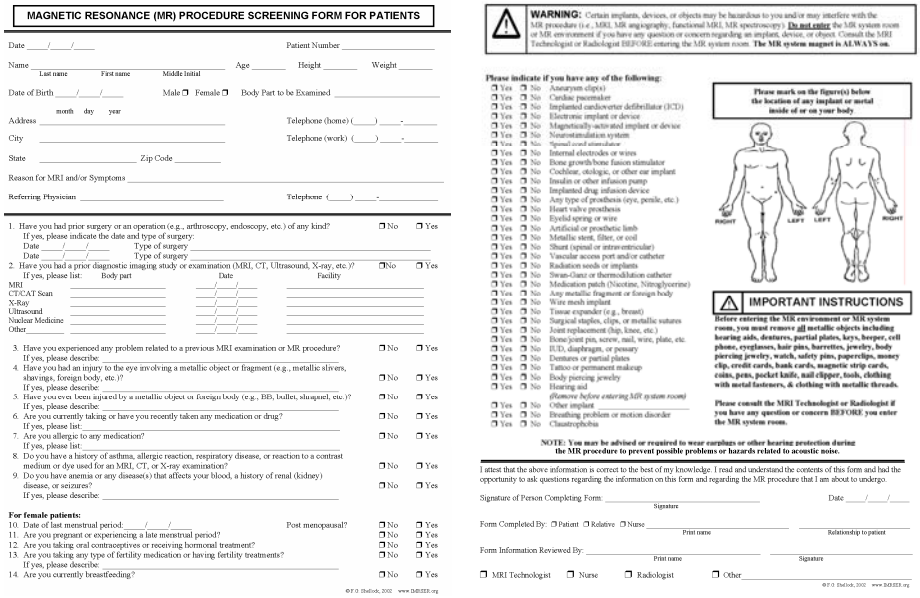
[*Portions of the text in this section were excerpted from MR screener documentation provided freely available on the web sites, www.IMRSER.org and www.MRIsafety.com with permission from Frank G. Shellock, Ph.D., FACC, FACSM]

Effective screening procedures of patients and other individuals before entering the MR facility is one of the most critical components for conducting a safe program. This is an important aspect of protecting patients and individuals from MR system-related accidents and injuries. Most MR-related incidents have been due to deficiencies in screening methods and/or a lack of properly controlling access to the MR environment. Hence, persistent vigilance and attention to detail must be a part of every responsible study. Regardless of the duration, every person who enters the Magnet Room should be made aware of the dangers as well as sufficiently cautioned about not brining in anything into the room under any circumstances. **It goes a long way to always advise and oneself be advised that the MR system magnet is ALWAYS on.**

Magnetic Resonance (MR) Procedure Screening for Patients

Screening patients for MR using *Magnetic Resonance (MR) Procedure Screening for Patients* must be done before each scanning session. This should be conducted by a person who has successfully completed the CFMI safety training course (§6.1 Safety Training). This person is expected be familiar with the information contained on the screening forms for patients and individuals. Subjects must complete IRB approved consent and MRI safety screening forms prior to entering the MR room and being scanned, and copies of these documents must be left at the imaging center.
Comprehensive patient screening involves the use of a printed form to document the screening procedure, a review of the information on the screening form, and a verbal interview to verify the information on the form and to allow discussion of concerns the patient may have.
A hard copy of the screener is available at CFMI, and it can also be downloaded from the web sites, www.IMRSER.org and www.MRIsafety.com

This form is used to ascertain if the patient has an implant that may be contraindicated for the MR procedure (e.g., a ferromagnetic aneurysm clip, pacemaker, etc.) or if there is any condition that needs careful consideration (e.g., the patient is pregnant, has a disability, etc.).



MAGNETIC RESONANCE (MR) PROCEDURE SCREENING FORM FOR PATIENTS

Date ____/____/____ Patient Number _____

Name _____ Age _____ Height _____ Weight _____
Last name First name Middle Initial

Date of Birth ____/____/____ Male ❒ Female ❒ Body Part to be Examined _____
month day year

Address _____ Telephone (home) (____) ____-_____

City _____ Telephone (work) (____) ____-_____

State _____ Zip Code _____

Reason for MRI and/or Symptoms _____

Referring Physician _____ Telephone (____) ____-_____

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? ❒ No ❒ Yes
If yes, please indicate the date and type of surgery:
Date ____/____/____ Type of surgery _____
Date ____/____/____ Type of surgery _____
2. Have you had a prior diagnostic imaging study or examination (MRI, CT, Ultrasound, X-ray, etc.)? ❒ No ❒ Yes
If yes, please list: Body part Date Facility
MRI _____ ____/____/____ _____
CT/CAT Scan _____ ____/____/____ _____
X-Ray _____ ____/____/____ _____
Ultrasound _____ ____/____/____ _____
Nuclear Medicine _____ ____/____/____ _____
Other _____ ____/____/____ _____
3. Have you experienced any problem related to a previous MRI examination or MR procedure? ❒ No ❒ Yes
If yes, please describe: _____
4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)? ❒ No ❒ Yes
If yes, please describe: _____
5. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? ❒ No ❒ Yes
If yes, please describe: _____
6. Are you currently taking or have you recently taken any medication or drug? ❒ No ❒ Yes
If yes, please list: _____
7. Are you allergic to any medication? ❒ No ❒ Yes
If yes, please list: _____
8. Do you have a history of asthma, allergic reaction, respiratory disease, or reaction to a contrast medium or dye used for an MRI, CT, or X-ray examination? ❒ No ❒ Yes
9. Do you have anemia or any disease(s) that affects your blood, a history of renal (kidney) disease, or seizures? ❒ No ❒ Yes
If yes, please describe: _____

For female patients:
10. Date of last menstrual period: ____/____/____ Post menopausal? ❒ No ❒ Yes
11. Are you pregnant or experiencing a late menstrual period? ❒ No ❒ Yes
12. Are you taking oral contraceptives or receiving hormonal treatment? ❒ No ❒ Yes
13. Are you taking any type of fertility medication or having fertility treatments? ❒ No ❒ Yes
If yes, please describe: _____
14. Are you currently breastfeeding? ❒ No ❒ Yes

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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 MRI Technologist or Radiologist BEFORE entering the MR system room. **The MR system magnet is ALWAYS on.**

Please indicate if you have any of the following:

❒ 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
❒ Yes ❒ No Implanted drug infusion device
❒ Yes ❒ No Any type of prosthesis (eye, penile, etc.)
❒ Yes ❒ No Heart valve prosthesis
❒ Yes ❒ No Eyelid spring or wire
❒ Yes ❒ No Artificial or prosthetic limb
❒ Yes ❒ No Metallic stent, filter, or coil
❒ Yes ❒ No Shunt (spinal or intraventricular)
❒ Yes ❒ No Vascular access port and/or catheter
❒ Yes ❒ No Radiation seeds or implants
❒ Yes ❒ No Swan-Ganz or thermodilution catheter
❒ Yes ❒ No Medication patch (Nicotine, Nitroglycerine)
❒ Yes ❒ No Any metallic fragment or foreign body
❒ Yes ❒ No Wire mesh implant
❒ Yes ❒ No Tissue expander (e.g., breast)
❒ Yes ❒ No Surgical staples, clips, or metallic sutures
❒ Yes ❒ No Joint replacement (hip, knee, etc.)
❒ Yes ❒ No Bone/joint pin, screw, nail, wire, plate, etc.
❒ Yes ❒ No IUD, diaphragm, or pessary
❒ Yes ❒ No Dentures or partial plates
❒ Yes ❒ No Tattoo or permanent makeup
❒ Yes ❒ No Body piercing jewelry
❒ Yes ❒ No Hearing aid
(Remove before entering MR system room)
❒ Yes ❒ No Other implant _____
❒ Yes ❒ No Breathing problem or motion disorder
❒ Yes ❒ No Claustrophobia

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

RIGHT LEFT LEFT RIGHT

IMPORTANT INSTRUCTIONS

Before entering the MR environment or MR system 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 clipper, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system 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.

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.

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

Form Completed By: ❒ Patient ❒ Relative ❒ Nurse _____ _____
Print name Relationship to patient

Form Information Reviewed By: _____ _____
Print name Signature

❒ MRI Technologist ❒ Nurse ❒ Radiologist ❒ Other _____

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Figure 8-1 Screening form for patients

Preliminary screening, fairly in advance to the actual scan session, helps to prevent scheduling participants that may be inappropriate candidates for MR examinations, which can improve efficiency and lower monetary penalties associated with late cancellations. After preliminary screening, the patient must still undergo the comprehensive screening in preparation for scan session.

Quick overview

Page one

Top section: Helps gather pertinent and up-to-date information about the patient, and contact information. This includes general patient-related information (name, age, sex, height, weight, etc.), as well as a reason for the MR procedure and/or symptoms that may be present.

Bottom Section: Requests information regarding prior surgery or operation, which can help determine if there may be an implant or device present that could create a problem for the patient. Information is also requested pertaining to prior diagnostic imaging studies that may be helpful to review for assessment of the patient's condition.

Page two

Top section: Advises not to enter the MR system room or MR environment if there is any question or concern regarding an implant, device, or object.

Middle section: Lists various implants, devices, and objects to identify anything that could be hazardous to the patient undergoing the MR procedure or that may produce an artifact that could interfere with the interpretation of the MR procedure. In general, these items are arranged on the checklist in order of the relative safety hazard (e.g., aneurysm clip, cardiac pacemaker, implantable cardioverter defibrillator, electronic implant, etc.), followed by items that may produce imaging artifacts that could be problematic for the interpretation of the MR procedure. Additionally, questions are posed to determine if the patient has a breathing problem, movement disorder, or claustrophobia.

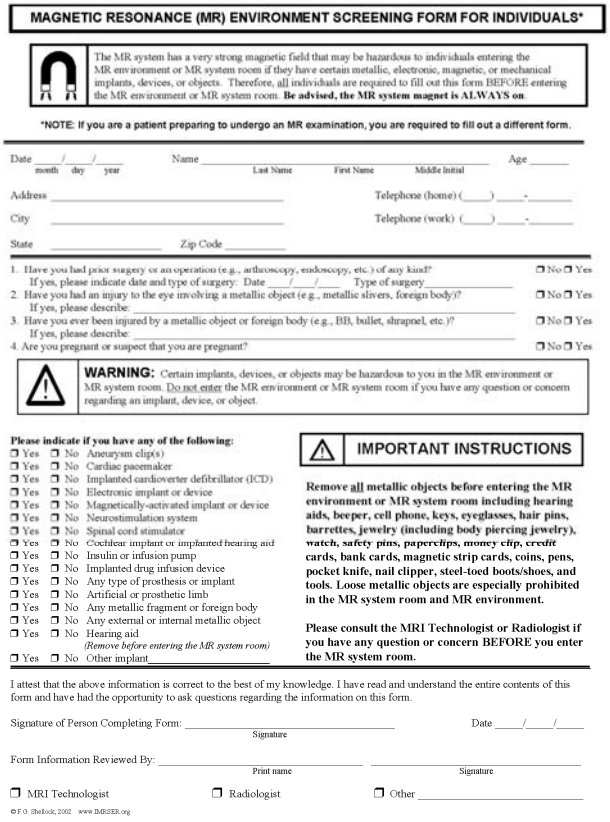
Figures of the human body are included on the second page of the form as a means of showing the location of any object inside of or on the body. This information allows the patient to indicate the approximate position of an object that may be hazardous or that could interfere with the interpretation of the MR procedure as a result of producing an artifact.

Lower section: Has Important Instructions for the patients before entering the MR environment. Importantly, undergoing previous MR procedures without incidents does not guarantee a safe subsequent MR examination. **A written screening form must be completed each time a patient prepares to undergo an MR procedure.**

An MR-safety trained person should review the completed form's content, and verify/clarify the information provided through a verbal interview, and allow discussion of any question or concern that the patient may have. This allows a mechanism for clarification or confirmation of the answers to the questions posed to the patient so that there is no miscommunication regarding important MR safety issues. In addition, because the patient may not be fully aware of the medical terminology used for a particular implant or device, it is imperative that this particular information on the form be discussed during the verbal interview.

Magnetic Resonance (MR) Environment Screening for Individuals

Before any "non-patient" individual (e.g., MRI technologist, support person, patient relative, visitor, allied health professional, physician, maintenance worker, custodial worker, fire fighter, security officer, etc.) is allowed into the MR environment, he or she must be screened by an MR-safety trained person. Proper screening for individuals involves the use of a printed form to document the screening procedure, a review of the information on the form, and a verbal interview to verify the information on the form and to allow discussion of any question or concern that the individual may have before permitting entry to the MR environment.



MAGNETIC RESONANCE (MR) ENVIRONMENT SCREENING FORM FOR INDIVIDUALS*

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.

Date ____/____/____ (month day year) Name _____ (Last Name First Name Middle Initial) Age _____

Address _____ Telephone (home) (____) ____-____

City _____ Telephone (work) (____) ____-____

State _____ Zip Code _____

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? ❒ No ❒ Yes
   If yes, please indicate date and type of surgery: Date ____/____/____ Type of surgery_____
2. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, foreign body)? ❒ No ❒ Yes
   If yes, please describe: _____
3. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? ❒ No ❒ Yes
   If yes, please describe: _____
4. Are you pregnant or suspect that you are pregnant? ❒ No ❒ Yes

WARNING: Certain implants, devices, or objects may be hazardous to you in the MR environment or MR system room. Do not enter the MR environment or MR system room if you have any question or concern regarding an implant, device, or object.

Please indicate if you have any of the following:

❒ 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 Cochlear implant or implanted hearing aid
❒ Yes ❒ No Insulin or infusion pump
❒ Yes ❒ No Implanted drug infusion device
❒ Yes ❒ No Any type of prosthesis or implant
❒ Yes ❒ No Artificial or prosthetic limb
❒ Yes ❒ No Any metallic fragment or foreign body
❒ Yes ❒ No Any external or internal metallic object
❒ Yes ❒ No Hearing aid *(Remove before entering the MR system room)*
❒ Yes ❒ No Other implant_____

IMPORTANT INSTRUCTIONS

Remove all metallic objects before entering the MR environment or MR system room including hearing aids, beeper, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry (including body piercing jewelry), watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, steel-toed boots/shoes, and tools. Loose metallic objects are especially prohibited in the MR system room and MR environment.

Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room.

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

Signature of Person Completing Form: _____ (Signature) Date ____/____/____

Form Information Reviewed By: _____ (Print name) _____ (Signature)

❒ MRI Technologist ❒ Radiologist ❒ Other _____

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Figure 8-2 MR Environment Screening for Individuals

Important Note: If for any reason the individual undergoing screening may need to enter the MR system and, thus, become exposed to the electromagnetic fields used

for an MR procedure, this person must be screened using the Magnetic Resonance (MR) Procedure Screening Form for Patients.

In general, magnetic resonance (MR) screening forms were developed with patients in mind and, therefore, tend to pose many questions that are inappropriate or confusing to other individuals that may need to enter the MR environment. Therefore, a screening form was created specifically for individuals that need to enter the MR environment and/or MR system room. A hard-copy of this form, entitled, Magnetic Resonance (MR) Environment Screening Form for Individuals, screener is available at CFMI, and it can also be downloaded from the web sites, www.IMRSER.org and www.MRIsafety.com

Quick overview:

Top section: Advises not to enter the MR system room or MR environment if there is any question or concern regarding an implant, device, or object. It also gathers pertinent and up-to-date information about the person entering the MR environment, and contact information. This gathers general individual-related information (name, age, date, and contact information).

Middle Section: Requests information regarding prior surgery or operation, which can help determine if there may be an implant or device present that could create a problem for the person preparing to enter the MR environment.
It also lists various implants, devices, and objects to identify anything that could be hazardous to the person entering the MR scanner room. In general, these items are arranged on the checklist in order of the relative safety hazard (e.g., aneurysm clip, cardiac pacemaker, implantable cardioverter defibrillator, electronic implant, etc.). To the right side, it has Important Instructions for the patients before entering the MR environment.

Lower section: **A written screening form must be completed each time a patient prepares to undergo an MR procedure.** An MR-safety trained person should review the completed form's content, and verify/clarify the information provided through a verbal interview, and allow discussion of any question or concern that the individual may have. This allows a mechanism for clarification or confirmation of the answers to the questions posed to the patient so that there is no miscommunication regarding important MR safety issues.
Finally, there is an Important Instructions section on the form that states: "Remove all metallic objects before entering the MR environment or MR system room including hearing aids, beeper, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry (including body piercing jewelry), watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, steel-toed boots/shoes, and tools. Loose metallic objects are especially prohibited in the MR system room and MR environment. Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room."

The proper use of this written form along with thorough verbal screening of the individual by an MR-safety trained person will prevent accidents and injuries in the MR environment.

REFERENCES

http://www.MRIsafety.com
http://www.IMRSER.org

8.1.2 Set Up and Scanning

- Only qualified persons may operate the MRI system (those having gone through the MRI Siemens training course).
- No one (including researchers and assistants) may enter the scanner room without completing a screening form and the MR Safety Training course.
- Subjects must sign the appropriate consent and screening forms before they are imaged.
- If there are any questions regarding a subject's compatibility with the magnetic field, one of the technical staff must be notified.
- Anyone entering the scanner room must first "de-metal" (empty pockets; remove jewelry, watches, wallets, beepers, hair clips; pens, clipboards etc.). It is better to have them remove everything from their pockets than to leave the potential for a serious hazard.
- Hearing protection (in the form of earplugs or headphones, or both) must be used when scanning all subjects.
- Double check wires on all equipment you use in the scanning room for loops which can cause serious electrical burns.
- The scanner bed will not support subjects weighing approximately 350 pounds or more.
- Don't use paper clips or other small metal objects (staples, etc.) around scanner. They tend to land on the floor and find their way into the magnet room and into the magnet
- In case of an adverse event the session is to be terminated immediately and the incident should be reported to the GU IRB and a copy submitted to the center director for evaluation and corrective measures.

For further information and guidance, please visit the Georgetown Institution Review Board website (IRB: http://ora.georgetown.edu/irb/). All studies conducted at the center are expected to adhere strictly to IRB approved protocols. Any incidents found in violation are to be reported to the GU IRB and a copy submitted to the center director for evaluation and corrective measures. It is the PIs' responsibility to be able to handle any Adverse Event associated with their study.

8.1.3 Log in/ out

All must sign into the scanning logbook and the online logbook (§3.6 CFMI New Scan Logging System), both, located next to the 3T operating console, as soon as they are setting up the room and using the facility. The time start is NOT the same as when they start scanning the participant, but when they start using the center. (Example: request time from 10:00AM - 11:30AM, billing starts at 10:00AM not 10:05AM) The time is not only representative of using the scanner but the equipment and room as well. The time end represents when you have finished cleaning up and others can come in and start setting up for the next session, not when the participant comes out of the scanner.

- It is important to make sure to record in all of the columns (date, PI, IRB#, Rx#, Scanner Operator, Subject ID, Time start, Time end) as failure to do so may result in additional charges or suspension of scanning.
- Subjects must be registered in the logbook prior to scan session
- Remember to start scanning session before entering the magnet room

8.1.4 Clean up

- Remember to **LOGOUT** of your scanning session

- Return all equipment to its labeled place on the shelves or in the drawers
- Place soiled linens in the laundry hamper outside the magnet room.
- Contaminated materials (excluding sharps) must be placed in the contaminated waste box in the magnet rooms.
- All sharps are to be placed in the plastic sharps container located in the magnet room and on the wall outside the control room. Sharps are never to be placed in any wastebasket.

No food or drink is allowed in the Magnet Console Room; no exceptions.

Any researcher who uses the MRI system is required to clean up. If the area is untidy when you arrive, or if equipment has not been returned to its proper position or default state, notify John VanMeter, Ph.D. by email. If you fail to notify John, you could be held responsible.

8.1.5 Broken equipment

All broken equipment and equipment failures should be reported immediately to John VanMeter, Tom Zeffiro or, Stan Fricke via email (see phone list for contact information). It is understood that equipment in such constant use will occasionally break, and given proper use – taught during Console Operation Training – one may not necessarily be held responsible for the equipment failure. Remember, it cannot be fixed unless it is known to be broken. It should also be remembered that anyone operating the console or using any accessory item located in the vicinity should have successfully completed the console operator training course.

9. Emergency Procedures (7-HELP; 7-4357)

9.1 Fire

In the event of a fire in the building, stop scan, remove participant from scan room, lock MRI room, and evacuate the center and building safely. Locking the Magnet Room will ensure that emergency personnel do not enter the room with their non-MR compatible equipment, which poses a great risk. It is important that as soon as the fire alarm is recognized that the scan is stopped **immediately**, and the MR technologist may NOT attempt to proceed scanning for any reason. This procedure should be adhered to with no exception, and failure to do so will have dire consequences.

9.2 Medical Emergency

Contact 7-HELP to send an emergency team to the center to attend to the patient. Upon calling for help, keep in mind that the emergency teams may not be familiar with the immense forces of the magnet. Be extremely cautious to alert everybody. If possible, remove the participant from the MR room, unless it would cause the participant more harm than good to move them.

9.3 Other

9.3.1 Emergency STOP Scan

Stop the Scanner - To stop a scan quickly, click Stop on the console. Make sure you and your assistants know the location of this control.

(**Note**: There is an additional emergency button above and to the right of the console which shuts down the whole system. Use this only when absolutely necessary. With this shut-down method, scanning cannot resume for approximately fifteen minutes.)

9.4 Emergency Phone Numbers

**** In case of emergency call: 911***

Fire, Police, Ambulance:	7-HELP (7-4357)
DC Emergency:	9-911
DC Police Non-Emergency:	9-311
John VanMeter Ph.D.	7-8767

9.5 Using the Squeeze-Ball to Signal an Emergency

During a scan, due to gradient switching, the scanner makes a fairly loud noise, which may prevent auditory communication of the subject with the operator. The squeeze ball is a small hand-held pneumatic device which is useful in getting the operator's attention during a scan. It produces a fairly loud sound that can be heard by the magnet operator, as well as anyone in the vicinity of the MR console. While in the magnet, subjects should be informed of and given the Emergency squeeze-ball in an easily accessible location. In case of an emergency during scanning, the squeeze-ball can be used to signal the operator to stop scanning. As this device is intended for emergency, it should be used sparingly.

9.6 Incident reporting

In the rare event that a subject reports any untoward or unexpected reaction to the scan (e.g. painful cutaneous sensation, nausea, etc.) the experiment is to be terminated and the incident reported to John VanMeter. Adverse events should also be reported to the GU IRB. A copy of all Adverse Events reports should be submitted to the center director. It is the PI's responsibility to take this class and be able to handle any Adverse Event associated with their study.

http://www.georgetown.edu/gumc/ora/irb/irb_caer.htm

A. Glossary of Acronyms and other terms

Authorized User (AU)

This is the CFMI representative who overlooks proper conduct of research scanning session. It is required that one be present at any scan involving human subjects. Adverse effect, equipment malfunction or any other incidents must be immediately reported to the AU

Institutional Review Board (IRB)

On behalf of Georgetown University, the Institutional Review Board's (IRB) major role is to safeguard the rights and welfare of all human subjects who participate in research projects conducted by Georgetown. All research projects involving human subjects or human material must be reviewed and approved by the IRB. All biomedical, social and behavioral research projects conducted by the faculty, the staff and students of the University are subject to the Policies and Procedures of the Institutional Review Board. Please visit the Georgetown University IRB website for further information: http://ora.georgetown.edu/irb/

Center Director

This is the director of the Imaging Center.

CFMI online logbook

This is the mechanism used for tracking and detailing scan sessions. Located on the web at http://cfmi.georgetown.edu/log_system. Please refer to section § 3.6 and 3.7 for usage guidelines. The online logbook must be utilized for every scan session.

Facilities Manager

This is a CFMI staff member who is in charge of all research equipment. This individual responds to inquiries about usage, maintenance and replacement.

Faculty attending scan

The center requires that a faculty representative from a research group conducting a pediatric scan is present at all such scans.

MRI Calendar

A mechanism used to book MRI scanning time. Located on the web at http://cfmi.georgetown.edu/calendar.php

MRI Console Operator

An individual who has completed both CFMI safety training and SIEMENS Console operation training and is authorized by the Center Director to conduct scans.

Principal Investigator (PI)

The Principal Investigator is the primary individual in charge of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project.

Piloting

This is a study that has been approved by the Center Director for researching and/or developing new studies/protocols.

Research accounts

1. Funded Account

   A research account set up with a financial agreement with CFMI

2. Unfunded Account

   A research account set up with a pending financial agreement with CFMI often called a pilot account.