DRAFT: Procedure Manual

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Procedure Manual

This binder provides information needed for a principal investigator to utilize the resources of the UC Davis Research Imaging Center (UCDRIC, or RIC). It provides an overview of the resources, and step-by-step procedures for accessing them. It provides information that will allow the principal investigator to understand how their own resources, such as computers and personnel, can be used in conjunction with the resources of the RIC to accomplish their research imaging goals.

I.   Types of imaging studies that can be done

The Center welcomes investigators with all types of imaging requirements. MRI protocols and pulse sequences are available for every organ system. The MRI system at the RIC is particularly optimized for brain imaging and cardiovascular imaging. Specialized pulse sequences include echo planar (EPI) and spiral fast imaging techniques, arterial spin tagging for tissue perfusion measurements, diffusion tensor imaging, single voxel spectroscopy, and a complete set of sequences for real-time cardiac and vascular flow imaging. The systems are equipped with the protocols and pulse sequences that are used in the clinical setting.

MRI imaging studies are considered in two broad categories: structural MRI and functional MRI. Functional MRI is usually abbreviated as fMRI. When the term "MRI" is used, it refers to both "structural and functional MRI" research projects. The term "MRI research" refers to clinical case studies, clinical research projects, and basic science research projects. The research projects can involve human imaging, animal imaging, or imaging of inanimate objects and tissue specimens. It is understood that in-vivo imaging involves patients as well as normal subjects. This distinction applies to animal studies as well as human studies. When the term "patient" is used, it refers to patients and normal subjects, and humans or animals as appropriate, unless stated otherwise.

II.   Carrying out an MRI research project: Start to finish

A. Submit a project proposal to MRUG

The RIC defines three types of MRI research proposals: regular, pilot, and supplemental pilot. Which proposal the principal investigator submits depends on whether or not the principal investigator has funding, whether or not the scanning protocol already exists on the imaging system, and whether or not the project is a continuation of a previously approved project.

Principle investigators that wish to use the MRI system with a known MRI scanning protocol, and who have funding to pay for the MRI scan time and technical support, should complete the "Regular Research Procedure Request Form". Prior to submission the principal investigator should talk with the Technical Director to resolve any questions about the project. The completed form should be submitted to the Magnetic Resonance User's Group (MRUG) for review and approval. Upon approval, a logon name will be setup on the MRI system, and personnel of the RIC (e.g., MRI Research Technologist) will be authorized to spend time on the project. The principal investigator can utilize the Web-based MR Scheduler to schedule time on the system. The MRI Technologist will run preliminary sessions if necessary.

The funding source for the project must be specified on the Regular Research Procedure Request Form. The MRUG will determine the cost of using the MRI system, based on standard charges. The RIC will charge the principal investigator for MRI system time, for the support provided by the RIC staff in the preliminary MRI sessions, as well as for support provided during patient scanning sessions. See section on Billing procedures and MRI Rate Schedule for current rates.

If there is no funding, then a pilot research project proposal needs to be submitted to the MRUG. MRUG will review the proposal and if approved, fund preliminary sessions and a certain number of patient sessions, at no cost to the principal investigator. The MRI physicist and technologist will help the principal investigator get the pilot project completed. See the included document "MRI Research Project Proposal Form and Instructions. Principal investigators that are setting up an MRI research project for the first time should see the included Help Guide entitled "Guide to Setting Up an MRI Research Project". Principal investigators that are setting up an fMRI research project for the first time should see the included Help Guide entitled "Sample Experimental Design for an fMRI Research Project".

If the principal investigator of a pilot project determines that additional scanning sessions are necessary to complete preliminary data for an extramural grant submission, he/she can submit a supplemental pilot research project proposal. MRUG will review the proposal and if approved, will fund a certain number of additional patient sessions, at no cost to the principal investigator.

B. Specific tasks for preparing a proposal to MRUG

1.   Develop the MRI Protocol

An MRI scanning protocol is a list of all the scans that will be done in the scanning session in chronological order, and a list of all the scan parameters for each scan. An MRI Scan Parameter Spreadsheet is included in this Binder. For each scan, the principal investigator fills in the spreadsheet with the parameter values. All MRI parameters and values must be included in the list. If the principal investigator has an MRI protocol that he/she knows will work (e.g. obtained from another MRI imaging center), it should be included in the project proposal to MRUG, and used to fill in the Scan Parameter Spreadsheet. The principal investigator should identify whether or not special software and/or hardware (e.g. a particular RF coil, special stimulus device) is required to do the protocol. Pilot project proposals do not require If parameter values and equipment

2.   Identify accessory equipment and operators

Each piece of accessory equipment needs to be described in the project proposals. The use of accessory equipment is an important aspect of FMRI projects. An FMRI project will require use of the "stimulus computers", which are Intel-based PCs running Windows 98 or higher. It will also require the use of specific stimulus presentation software, (e.g., the "Presentation" software package), and perhaps specialized hardware for stimulus delivery (e.g. sensory stimulation device, such as a thermode). The stimulus computers play back the program that presents audio and visual stimulus during scanning. The MRI research technologist or physicist will be expert with the use of these software and hardware items, and will be expert in the operation of the MRI video projection and audio system. The experimental paradigm that runs on the "stimulus" computer is typically developed in the

principal investigators lab by graduate students and or post-docs. These individuals should run the paradigm on the stimulus computers during the scanning sessions.

In general, help with experimental paradigm development is not provided by the RIC. However, it is possible that the principal investigator will find an acceptable paradigm in the RIC's library of paradigms. The principal investigator will be given access to the stimulus computers at the RIC (a generic login account and disk space allocation), so that the principal investigator or someone from his/her group can learn its operation.

Most structural MRI scans do not use accessory equipment during the scanning sessions. However, an important exception is scans that require IV injection of contrast agent. All requirements regarding IV injections must be described in the project proposal to MRUG. If contrast agent is used, then the individual performing the IV injection of the agent must be licensed and certified by the Hospital to do such injections. MRUG will assign an MRI research technologist that is certified to do these injections, if such a technologist is available. The principal investigator has the option of providing a nurse to do the injections, or, if the principal investigator, or someone that works for him/her, has the needed license and certification, they can be designated to perform the injection. The IV injection may be done with the aid of a power injector.

3.   Identify role of technologist relative to research assistants

The RIC will provide an MR technologist from its staff, who will be responsible for setting up and operating the MRI system in each scanning session. The MRI technologist assumes the role of MRI technologist. If the principal investigator is doing an fMRI project, the images are reconstructed by the MRI technologist using proprietary software on an SGI and or Linux workstation. The MRI technologist can also train graduate students and post-docs that are working for the principal investigator, in the operation of the MRI system and image reconstruction for fMRI. The MRI technologist will be a major asset to new principal investigators, because he/she will be an expert in all issues related to the operation of the MRI system and production of images. The MRI technologist assumes a broad set of responsibilities. For a complete listing, refer to the document in this Binder entitled "MRI Research Technologist: Specific Skills, Knowledge and Abilities". The MRI technologist reports to the RIC Technical Director, who allocates resources and oversees these support activities. It is important to emphasize that the RIC charges an hourly fee for the services of the MRI technologist. The principal investigator will have a lower cost per scanning session if he/she arranges for a member of his/her research team (e.g. graduate student or post-doc) to be trained to operate the MRI system. For details, see the MRI Rate Schedule in this Binder.

4.   Decide on method for receiving images from scanning sessions

Typically, the principal investigator will have a computer on the internet, ready to receive the image files after completion of each scanning session. Images will be transferred by the MRI technologist, or trained MRI operator. If they are regular MRI images, then it is most convenient for the MRI technologist to send them to a DICOM client or server, directly from the MRI system. Using this method, the principal investigator receives the images immediately after completion of the scanning session. To use this method, the principal investigator must have a DICOM server or client, and must provide the MRI technologist with Internet Address, AE Title, and Port Number of the server or client. Alternatively, the

MRI technologist can send DICOM images to one of the SGI workstations (typically 152.79.52.13) at the RIC, to which the principal investigator can logon using the guest account (guest, ucdmri) and transfer the images via FTP. The principal investigator should provide the e-mail address of a contact person in the principal investigators lab, for data transfer. This person will be notified when the images are ready for transfer by ftp.

For multi-site clinical research studies in which UC Davis routinely participates, the MRI technologist archives the images on a GE optical disk, and mails the disk to the Reading Center of the research study. However, because GE optical disks can be read only by the optical disk drive on the MR system, they cannot be used for transferring images between the MRI system and individual laboratories. As a last resort, the MRI technologist or trained operator can write a CD-ROM of the images, for delivery to the principal investigator.

If the principal investigator is doing an fMRI project, the images are reconstructed using proprietary software on an SGI or Linux workstation. Reconstruction is done by the MRI technologist or trained operator who also performs the fMRI scanning session. The principal investigator should provide the e-mail address of a contact person in the principal investigators lab, for data transfer. This person will be notified when the fMRI images have reconstructed and are ready for transfer by ftp. The guest account on the SGI workstation (152.79.52.13, guest, guest2N) or Linux Workstation (152.79.52.168, frecon, 1Coron) is used for transferring fMRI images. Optionally, the MRI technologist can make a CD containing the image data that can be mailed to or picked up by the principal investigator.

5.   Obtain Human Subjects Review Committee (HSRC) Approval.

For pilot projects, the principal investigator can utilize one of the approved HSRC protocols maintained by the RIC Technical Director. Alternatively, the principal investigator can write a specific Human Subjects protocol for their project. It takes a couple of months for a new protocol to be approved. The Technical Director maintains the following two protocols, for use at the RIC: "Development of New Techniques for Functional Magnetic Resonance Imaging of the Brain", and 2. "Development of New Software Capabilities for Use with the Signa Cardiovascular Magnetic Resonance (CVMR) System". These are included in this binder. The principal investigator should review these to be sure that they are appropriate for their research project. These protocols are designed only for use in pilot projects only. Principal Investigators are expected to have their own protocols for supplemental pilot and regular research projects.

C. Fine-tuning the protocol of the approved research project

New MRI research projects typically require at least one, and often several, scanning sessions to set up the MRI protocol and confirm that it works as it should. These preliminary MRI sessions can be done with phantoms and or normal subjects. These sessions are needed for a wide variety of specific reasons. They may be needed to test a new slice alignment procedure, test a custom pulse sequence obtained from an outside research group or MRI system vendor, validate image quality, or optimize parameters for specific imaging objectives. Another important reason to run preliminary studies on normal subjects is to test accessory equipment and software. For example, in an fMRI project, it may be determined that an entirely new experimental paradigm needs to be developed. The paradigm must be created with a software

package such as the "Presentation" software package available on all RIC personal computers, or other software package. The paradigm must then be tested on the "stimulus computers" during an actual MRI scan. The Technical Director can estimate how many preliminary sessions will be needed. Often, the first patient scanning session is also considered to be a test, to provide images for the principal investigator to run image analysis, and confirm that the images are of the correct type and of sufficient quality for the project objectives.

In general, the preliminary sessions will be performed on a time frame set by the Technical Director. All preliminary sessions are scheduled on the Web-based scheduler (http://calendar.netscape.com, described below), so that the MRI system time is reserved. The Technical Director authorizes an MR physicist and or MRI technologist to perform the tasks necessary for these sessions. These tasks might include developing a modification to a custom pulse sequence, developing a special phantom, or checking that certain hardware is available and works well. The next step will be getting the MRI protocol keyed into the MRI system, and running phantom studies and normal subjects for testing the protocol. The MR physicist or MRI technologist may require assistance from the PI, such as providing a graduate student to help with the preliminary sessions, or recruiting a human subject to be scanned for the sessions.

D. Final preparations for the scanning sessions

There are several "final preparations" that must be carried out by the principal investigator prior to the first scanning session. These steps are performed after the principal investigator has received approval to do the project from the Magnetic Resonance User's Group (MRUG).

1.   Approved HSRC protocol and consent forms ready

To perform an MRI scan on a patient, there must be an APPROVED Human Subjects Review Committee Protocol for the project. Photocopies of the Human Subjects Review Committee (HSRC) protocol, including copies of the Consent Form, the Bill of Rights, and the MRI Screening Questionnaire, must be stored in the MRI tech room. Copies of the Bill of Rights and Screening Questionnaire are stored in the MRI tech room, for general use. Prior to scanning, the Consent Form must be signed by the patient, and the patient must be given a copy of the signed Consent Form along with the Bill of Rights.

2.   PI ready to setup and run accessory equipment

Generally, the principal investigator is responsible for setting up and running accessory equipment during the scanning sessions. The MRI physicist or MRI technologist will assume this responsibility, if necessary. Graduate students and post-docs that are being trained to operate the MRI system must also learn to operate the accessory equipment.

3.   MRI protocol is ready for scanning sessions

Prior to running a scanning session on a patient, the principal investigator must confirm that the protocol was keyed into the MRI system and tested, and is ready to use. This preparation is done during the preliminary scanning sessions.

4. MRI system time has been scheduled

Once the preliminary sessions have been completed, the principal investigator is ready to schedule scanning sessions. The principal investigator can reserve time on the MRI system by logging into the web-based scheduler, and making an appointment. For details, see section below on How to schedule time on the MRI system.

5. PI has confirmed that Tech is available to operate the system

In scheduling a scanning session, the PI must confirm that the individual assigned as the MRI Technologist is available at the proposed time. Principal investigators may find that having a post-doc or graduate student trained to operate the MRI system provides greater flexibility in scheduling. Training is provided by the MRI technologist during scanning sessions, and or in a formal training program (see below).

6. Principal investigator has recruited and can manage patient

Each principal investigator is responsible for recruiting the patient to participate in the research project. He/she is responsible for having the patient read, understand and sign the consent form from the approved HSRC protocol. He/she is responsible for transporting the patient to/from the Imaging Center. Informed consent must be obtained from each patient, either at the Imaging Center or prior to arrival. Principal investigators should provide at least one assistant, which may be themselves, to help the patient during the scanning session. This assistant will help with preparing the patient prior to the scanning session, with answering patient's questions as they arise during the session, and with supervising patient discharge.

7. Computer ready in principal investigator's lab to receive images

Principal investigator has a computer on the internet, ready to receive the image files after completion of the scanning session. The method of transfer was detailed in the project proposal.

E. Completing MRI Scanning Session Information Form

While the scanning session is in progress, the MRI technologist fills in the Official MRI Scanning Session Information Form. The Principal Investigator reviews and co-signs the form at the end of the session. The form records patient information, as well as the time in and time out from the MRI suite, the different scans run, and description of any difficulties, including scans that had to be redone, that prolonged the total time using the MRI system. The total time that the MRI system was collecting data (i.e. a pulse sequence actually running) is also recorded. Completed forms are kept on file in the MRI suite.

F. Completing the project

Projects should be completed within 12 months of MRUG approval. Final reports are not required. However, investigators submitting supplemental pilot project proposals must describe in that proposal the results of their pilot project.

III.   Training to operate the MRI system

If the principal investigator anticipates frequent usage of the MRI system and would like to become more self-sufficient, they, or an associate, can be trained to independently operate the MRI system. Three types of training, labeled *A*, *B*, and *C*, are listed below. Type *A* is the fastest and most direct training to obtain Level 1 authorization for operating the MRI system. The formal training course, described in *B*, can be taken in lieu of, or in addition to, training described in *A*. Upon successful completion of type *A* or *B* training, Level 1 authorization will be granted. Training described in *C* is optional. However, individuals seeking higher levels of authorization are required to enroll in or attend these courses, as well as meet other requirements.

There are three levels of authorization for operating the MRI system. "Level 1" authorization allows the individual to operate the MRI system only for the specific research project that he/she is directly involved with (either as PI or working for PI). "Level 2" authorization allows the individual to serve as an MRI technologist. An MRI technologist understands general operation of the MRI system, and can operate the MRI system for someone else's research project. The MRI technologist is capable of keying in a new MRI protocol on the system, including testing it on phantoms and or human subjects. "Level 3" authorization allows the individual to serve as an MRI physicist. With this authorization, the individual is able to operate the MRI system for any research project, and in addition, the individual is able to develop and test new pulse sequences on the MRI system, using the research mode of the MRI system and the EPIC pulse programming language. Level 1 authorization would typically be granted to a graduate student or post-doc in a specific principal investigator's lab. Level 2 or 3 authorizations are granted to individuals only if they have demonstrated MRI knowledge comparable to that taught in graduate-level university courses in MRI, and have demonstrated considerable practical experience operating MRI systems. Level 2 authorization would typically be granted to a senior graduate student or post-doc employed part time by the RIC to perform scans for principal investigators. Level 2 authorization is automatically granted to any person hired by the RIC as an MRI technologist. Level 3 authorization would be granted to an engineering or physics graduate student in his/her final years of their graduate program in MRI physics. Level 3 authorization is automatically granted to any person hired as MRI physicist at the RIC. It would also be granted to any person hired as an MRI technologist that has prior training in pulse sequence development.

A. Observe, operate with supervision, and operate independently

The individual seeking Level 1 authorization should observe (and take detailed notes) of the scans in his/her own project that he/she will eventually perform. After 2-4 sessions of observation, followed by 2-4 sessions of running the MRI system under supervision by the MRI technologist, the individual should be able to run the MRI system independently. After 2-4 sessions of operating the MRI system independently (with post-session review by the MRI technologist), the individual will be eligible for Level 1 authorization. The individual will be expected to study the documents on MRI safety provided in this Binder. A multiple choice examination must be completed and passed. Level 1 authorization is granted after successful completion of operating the MRI system independently, and passing the written examination.

B. Take formal training course

A training course, developed by the MRI Technical Director, will be given by the MRI technologist at least once each year. The course will consist of lectures and hands-on training on the MRI system. There will be an examination consisting of written and laboratory components, which will test basic theory and practical knowledge regarding MRI operation. Level 1 authorization will be granted to those passing the examinations.

C. Enroll in MRI courses

Individuals seeking Level 1 authorization on the MRI system are encouraged to take the Technical Director's Course, BIM 241 (Biomedical Engineering Graduate Course). BIM 241 is a non-mathematical introduction to the physics and operation of the MRI system. This can be audited by arrangement with the Technical Director. Upon completion of the course, the individual should feel comfortable with the idea of operating the system. A draft of a book that covers the material of the course will be available to enrollees of the course. Reading assignments will guide the individual through the most important material. Individuals seeking Level 2 authorization are encouraged to enroll in BIM 241 and BIM 246. BIM 246 provides a mathematical introduction to MRI technology. Individuals seeking Level 3 authorization are encouraged to enroll in BIM 247 and BIM 248 in addition to BIM 241 and BIM 246. BIM 247 and 248 are advanced courses in MRI physics and signal processing. Individuals seeking Level 2 or 3 authorizations must demonstrate MRI knowledge comparable to that taught in these recommended courses.

D. Obtain authorization to run the MRI system

Authorization, and the authorization level, are granted by the MRI Technical Director based upon the requirements met by the individual. The Technical Director maintains records of each individual that is be trained to use the MRI system, and maintains performance records of each person that has been authorized.

IV. More details about specific topics

A. Information about MRUG

The Magnetic Resonance User's Group is a committee of principal investigators selected from the UC Davis Faculty having expertise in MRI and its applications. The purpose of the MRUG is to insure that research projects involving MRI are able to benefit from the MRI resources of the RIC. All UC Davis campus faculty members, as well as post-docs and graduate students under faculty sponsorship, are welcome to submit a proposal to MRUG for a research project. For each submitted proposal, each MRUG committee member completes a standard evaluation form. A copy of that form is included in this Binder. The evaluation establishes whether the experimental design and MRI protocol in particular, is well designed with a reasonable chance for success.

B. Logon names to identify approved projects

In order to do any MRI research project, the principal investigator will need a specific login name on the MRI system, which identifies the project. Logon names are created on the MRI system for projects approved by the MRUG. The login name must be used for all system time

devoted to the project. Principal investigators involved in multiple projects may have several login names on the MRI system. Principal investigators should use each of these login names only for the specific project for which it was created. Each login name will be removed after its corresponding project is completed. By promptly removing login names, the number of names will be kept as small as possible. Roughly, the number of login names on the MRI system will be equal to the number of active research projects utilizing the system.

C. How to schedule time on the MRI system

All scanning sessions on the Research Imaging Center (RIC) MRI systems will be scheduled on the calendar.netscape.com calendar. To use this calendar, the principal investigator goes the following site

 http://calendar.netscape.com

At the login screen

Screen name: ucdmri
Passwd: imagingcenter

Click Sign in:

A calendar with all the scheduled scanning sessions is displayed. The principal investigator can reserve any available time interval for his/her scanning session(s). If a time slot is not taken, the principal investigator can reserve it by entering an appointment into that time slot. In addition to setting the start time, the principal investigator must be sure to set a realistic duration. If an MRI technologist is needed to operate the MRI system or setup accessory equipment, then he/she must be notified. He/she can be notified with the e-mail "Tell a Friend" feature of the scheduler. Appropriate e-mail addresses can be obtained from the Technical Director. The MRI technologist must explicitly confirm the date and time of the scanning session. Obviously, the session cannot be done unless a person authorized to operate the MRI system is present. The MR technologist must be considered part of the principal investigator's team, with whom the principal investigator must coordinate the time when scanning sessions are done. A grad student or post-doc that works in the principal investigator's lab can be trained to operate the MRI system and thereby provide greater flexibility with scheduling.

Principal investigators must be conscientious in removing appointments for the MRI system that are not going to be fulfilled. The principal investigator must put their phone number and e-mail address in the notes section of the appointment. No one is allowed to schedule on top of an existing appointment. However, if there is a compelling need (e.g. patient schedule) for a particular reserved time slot, principal investigators may phone or e-mail the principal investigator that has that reserved time slot, to confirm their use of it, or to ask if a switch is possible.

D. Hours of access to the MRI system

The MRI system can be scheduled 24 hours/day, seven days a week, in accordance with any restrictions listed on the web-based scheduler. The cost of using the MRI system varies significantly with the time of day. For details, see the MRI Rate Schedule in this binder. Level 1 operators may operate the MRI system only during the weekday hours matching the GE service contract (7 AM -4 PM). Level 2 operators may operator the MRI system at any time.

Level 3 operators may operate the MRI system for research projects and pulse sequence development at any time. A Level 1 operator may operate the system in the evening if prior special approval is given by the Technical Director. Special approval might be given, for example, if no scanning sessions are on the subsequent morning's schedule, or if a level 2 or 3 operator is available on site or by phone to help with any problem.

E. MRI system use for technical developments

The Technical Director is authorized to specify how the MRI system time is used during unscheduled times, defined as times when no scanning sessions are scheduled on the web-based scheduler. The Technical Director will allocate this unscheduled time for activities that improve the infrastructure of the MRI suite, such as research pulse sequence development and testing, additional diagnostic procedures by MRI service personnel, room clean up, software and device installation, and refinement and testing of user protocols. Generally, activities which will potentially enhance the capabilities and stability of the MRI system will be approved. Individuals requesting time for pulse sequence development and testing must have level 2 or 3 authorizations. The Technical Director will grant time in blocks of 1 to 8 hours, to individuals with appropriate authorization and projects. If necessary, the Technical Director may schedule, on the web-based scheduler, up to 8 hours per week of evening and night hours for research and development of new pulse sequences and techniques. There is no charge for use of the MRI system for technical developments, if such use is approved by the Technical Director.

F. MRI safety procedures

Safety is an essential part of the training to operate the MRI system. The precautions that must be taken working around the strong magnetic field and other components of the MRI system are learned by observing safety precautions taken during scanning sessions, discussing safety precautions with the MRI technologist, and reading the documents on MRI safety in this binder. Safety information is provided as part of the training program, and all prospective MRI operators are tested for their understanding of safety precautions. All faculty, staff and other individuals operating and or involved in the use of the MRI system are required to study MRI safety issues, as described in the documents on MRI safety in this Binder.

G. GE Medical Systems Service

The RIC has a service contract with GE that provides repair of the system between the hours of 7-4 PM, M-F, excluding holidays. GE Insight is a telephone and remote access for GE Service that is available 24 hours/day, seven days a week. GE Service can sometimes diagnose and correct system problems remotely. The Insight GE engineer gives instructions to the MRI operator to correct the problem. If a problem occurs outside of service contract hours, GE Insight first tries to correct the problem remotely with assistance from the MRI operator. If the problem cannot be corrected, the MRI system will be unavailable (i.e., "down"), until GE service can correct the problem during service contract hours. This means that problems caused by individuals working at night and weekend can have an adverse effect on scheduled projects during the weekend, and during the week as well.

GE Medical Systems Service reserves system time weekly for preventive maintenance. These times are reserved in the web-based scheduler.