

Ansini MRI Research Scanner User Guide

Outlined below is a guide to the research operations of the Ansini MRI scanner within the Department of Radiology. Currently this facility includes a 3.0 Tesla GE Discovery MR750 scanner, which is solely dedicated for Research use. On occasion, it may be possible for research studies to be conducted through the Core by using one of the clinical scanners due to vendor, campus location, or field strength requirements. Please note that these are not routinely done and are usually challenging to implement, and have scheduling constraints. Please contact MRI Research if you have any questions about this.

These guidelines have been developed by the MRI Research Operations Group. Current Operations Group members are:

David Alsop, PhD	Director of MRI Research
Leo Tsai, MD, PhD, MSc	Interim Director of Clinical MRI and Director of Oncologic Imaging
Martin P. Smith, MD	Medical Safety Officer of MRI Research
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Contacts:

Scheduling:

MRIResearchScheduling@bidmc.harvard.edu

All other questions:

MRIResearch@bidmc.harvard.edu

1. Types of studies appropriate for use of the Ansini MRI Research Scanners:

The scanners is intended to support research, which may include technical development of MRI methods, studies evaluating MRI as a diagnostic or physiologic marker, studies using MRI as a marker or measure in other kinds of research, and clinical trials using MRI as an indicator of response. While the scanners are designed for human studies, studies of non-biological or biological specimens and animal models may also be suitable. Please contact MRI Research if you have any questions about the suitability of your study.

Though our scanner is intended for use by BIDMC affiliated personnel, but we also encourage external collaborators to use the scanning facility, especially if they plan to include staff or patients at BIDMC in their research.

Studies involving patients who require special medical monitoring or assistance are performed on the scanners, but consultation to assure appropriate medical facilities and staff is required. Please contact MRI Research and we will discuss any special medical issues related to a potential study with the Medical Safety Officer.



2. How to get started with studies:

To begin a study, you will need human subjects or animal research approval through the BIDMC CCI/IRB, IACUC, or another appropriate regulatory body, and a source of funding for the scans. Since MRI has specific contraindications and safety issues, we recommend contacting MRI Research for advice on appropriate screening and other safety issues prior to submitting a human subject's protocol.

Rates are outlined below in *Section 4: User Fees*. If you do not have funding, you may apply for a limited number of internally funded pilot scans to obtain preliminary data for publication and grant submissions. Information regarding Pilot Studies can be found in *Section 5: Pilot Studies*.

Prior to using our facilities, we ask that you complete a "Request for MR Scan Time Form." This provides us with the information that we need to better manage the scanning, scheduling, and billing of your study. On this form, we ask for information on the scanning procedure required. We will also request a copy of the IRB protocol, consent form, and IRB approval letter. If your study involves the use of a contrast agent or any other study medication, we ask that you also submit a copy of your Part E.

Any nonstandard hardware, devices, or software must be discussed with MRI Research before use. There may be additional test and safety concerns. If you cannot specify the detailed scanning protocol, we ask you to please contact MRI Research and we will work with you to develop an appropriate scanning protocol. These protocols must be specified before scheduling because the information is needed to estimate scan time and determine necessary personnel and materials.

If you find that you need to perform tests in order to select the protocol and scan time for your study while submitting your "Request for MR Scan Time Form", you may request a few hours of pre-protocol development time with the MRI Technologist. This time is provided at no charge when considered necessary. Please make note of this on the Request for Scan Time Form in the appropriate section.

Once we have confirmed by e-mail that we have all of the required information and that your study has been approved by the Director of MRI Research and/or the MRI Research Program Manager, you may begin to schedule your studies. Scheduling is currently handled by e-mail, and the schedule can be viewed on our website. Please see more information on scheduling below in *Section 6: Scheduling Scanner Time*.

Before we can begin scanning subjects for your study, we require that all of the study personnel who will be entering the MRI scanning environment complete necessary safety measures. This includes an in-person New User Orientation, the review of an MRI Safety Training module, and the completion of an Employee MRI Safety form. Please see information below on MRI Safety Training.

- All staff present in the MRI environment are required to have an MRI Safety Form on file in MRI Research and complete the MRI Safety Training Module via myPATH, annually.
 - To request access to the MRI Safety Training module, please send an email to MRIResearch@bidmc.harvard.edu so that it may be assigned to you. Once assigned, you will need to complete the module and email your myPATH completion certificate to MRIResearch@bidmc.harvard.edu so that we may keep them on file.
 - *Note:* For external users without access to BIDMC's myPATH training, we will ask you to review and complete the BIDMC training on one of the computers in the MRI Research facility during your orientation.
- All study staff that will accompany patients into the MRI suite are required to provide their emergency contact information, in the case of inclement weather or other emergencies that would require study cancellation on short notice.
- All patients and human subjects who undergo scanning in the research MRI facility must: 1) provide written consent for each session, and 2) complete the MRI Research Safety Screening checklist.

3. Services Provided:

In addition to access to the scanner, the Ansin MRI Research facility provides the following services:

Technologist Support:

An MRI Technologist will be provided to perform the scans. We currently require that all human subject scanning be performed under the direct supervision of a licensed MRI technologist or other qualified personnel. The technologist support will be provided as part of the scanning charge.

Image Transfer and Management

Routine archiving of images and providing images via digital transfer is provided as part of the scan. For users outside of BIDMC, it is the responsibility of the study teams to set-up any needed data transfer agreements for receiving study images. Converting to other formats may be possible. Imaging data will be kept for at least 6 months from acquisition. After that point, it is the responsibility of the PI to handle and store their data. Please contact MRI Research with any questions.

Image Post-processing:

Technologists or other Ansin MRI Research Staff may be able to provide necessary image post-processing and analysis. An additional fee may be required. Please contact MRI Research with questions about image processing needs.



MRI Compatible Equipment:

The facility can provide MRI compatible physiologic monitoring, power injector, IV infusion pump, MRE, and fMRI visual and audio presentation capabilities. Please contact MRI Research with questions regarding equipment compatibility.

Subject Accompaniment:

A member of the study team is required to remain at the scanner during the entirety of the scan protocol. If no member of the study team be available to remain with the subject, please indicate this at the time of scheduling. In this case, the MRI Research Team will see if they are able to provide support by providing a member of our staff to accommodate the absence. Please note that a surcharge will be billed for this service.

4. User Fees:

The billing rates below have been established to support the maintenance and improvements of the imaging capabilities as well as the necessary staff for operation. When applicable, the rate includes services of a technologist to operate the scanner and transfer the data after it has been acquired.

The rates do not include any professional services related to consultation with MR scientists and physicians, study interpretation, specialized RF coil development, new sequence development for special experiments, etc. Costs for this support should be discussed with the Director of MRI Research and/or the individual scientist or physician providing support.

Time for technical development is available to BIDMC MRI Research Faculty performing tests and development of sequences in support of current and future scanning capabilities.

Each study requires 15 minutes for set-up and break-down of equipment. For example, a 1 hour slot allows for 45 minutes of scanning and 15 minutes for set-up and break-down. Studies will be charged in increments of 30 minutes. Please contact MRIResearch@bidmc.harvard.edu if you are planning a budget for a future study as the fees are subject to change.

*** The rates below are periodically reviewed and adjusted to reflect actual costs***

Service	Rate			
	Internal Federal/Nonprofit	Internal Industry/For-profit	External Federal/Nonprofit	External Industry/For-profit
MRI Usage with Technologist*	\$550/hour	\$1000/hour	\$825/hour	<i>Please Inquire</i>
Contrast Agent	\$60/scan	\$100/scan	\$90/scan	<i>Please Inquire</i>
Contrast Supplies (no agent)	\$25.00/scan	\$60/scan	\$37.50/scan	<i>Please Inquire</i>
Power Injector Kit	\$50/kit	\$50/kit	<i>Please Inquire</i>	<i>Please Inquire</i>
Subject Assistance Fee	\$50/hour	\$50/hour	<i>Please Inquire</i>	<i>Please Inquire</i>
Pregnancy Testing	\$18/person	\$18/person	<i>Please Inquire</i>	<i>Please Inquire</i>

An invoice will be generated monthly and sent to the appropriate billing contact. Internal users may use a BIDMC account and external users can pay by check. All payments should be made within 30 days from receipt of the invoice. Failure to pay may result in a hold on scheduling additional subjects until overdue payments have been received.

QA Phantom Scans:

A phantom scan to test the protocol to send to a sponsor at the beginning of the study or after scanner modifications, such as an upgrade, will be free of charge. Studies that require phantom testing on a regular basis (i.e. quarterly) will be charged the usual hourly rates.

5. Pilot Studies:

Researchers may be able to conduct MRI projects without external or internal funding provided the experiments are run to collect data for the purpose of validating the protocol and collecting data for grant submission processes. The proposal for all new pilot studies must be reviewed and approved. The proposal consists of a “Request for MR Scan Time Form,” the IRB approval letter, the protocol, and the informed consent form. The proposal should include the description of need, specific aims, and justification for the request. The type of scan and the resources that the study will use will be reviewed. Pilot studies should not require more than 20 hours of scan time.

The proposal will be evaluated and approved by the Director of MR Research and/or the MRI Research Program Manager. The review process will determine if the proposed research is appropriate given the technology available and whether the investigative team is prepared to carry out and analyze the experiment. The likelihood of scientific and funding success, along with scanner availability, will be key factors in the consideration for approval. The investigator and/or study coordinator will be notified via email of the pilot study approval.



6. Scheduling Scanner Time:

The BIDMC Ansin MRI Research Facility is committed to delivering the best MRI Services to investigators and their study teams in the most efficient manner. MRI is a valuable and expensive resource. Efficient use of this instrument is essential to provide services in an equitable manner and to keep costs from escalating.

- Scanner hours for the 3T are typically from 8:00am to 5:00pm Monday – Friday.

A calendar displaying the current MRI schedule is available on the MRI Research website. You will be provided with the link to the schedule, along with the password, once your project has been approved. Scans for approved projects will be scheduled by submitting an email to MRIResearchScheduling@bidmc.harvard.edu. When requesting scans, please send separate emails per subject and visit and include the following in your emails for each request:

1. PI Name and Contact Information (Phone and E-mail)
2. Project Title for Study
3. Which Magnet Required
4. Date for Scan Requested
5. The Preferred Start and End Time of the Scan (REMINDER: Time requested must include study set up and breakdown)
6. Subject Name and Study Identification Name
7. Medical Record Number (for subjects receiving contrast only)
8. Other Special Requests, e.g. Required Equipment, etc.

Investigators must arrive at a minimum of 20 minutes prior to the study if consent has already occurred. If the subject has not yet been consented, the investigator must arrive 30-45 minutes prior to the study so that they can consent their subject prior to their scan time. We highly encourage consenting of subjects before arrival at the MRI suite because there is limited private space available for use in the consenting process. If private space is needed, please add that information to the scheduling request email.

Each principal investigator is responsible for obtaining and maintaining documentation of Informed Consent Forms for their study. Signed Informed Consents are not to be housed at the MRI Research area.

Upon arrival to the MRI Research Suite, all subjects will complete an MRI Safety Screening Form. To avoid delays/cancellations, we strongly encourage all investigators and their study staff to prescreen recruited subjects for possible MRI contraindications. Examples of MRI Screening Questions are reviewed with the study team at the New User Orientation. Please do not hesitate to contact us at MRIResearch@bidmc.harvard.edu if you have any questions regarding MRI Safety. Screening ahead of time will ensure that our team has ample time to investigate possible contraindications for MRI.

MRI Research will store all safety forms for a period of 6 months. If MRI Safety Forms are required in study records, please be sure that the MRI Research Team is aware of this so that the original or a copy of the form can be provided to you.



Cancellations:

MRI is a valuable resource. As soon as you become aware that you will not be using a slot, please let us know by emailing the cancelled study information to MRIResearchScheduling@bidmc.harvard.edu. If the study team becomes aware of the cancellation on the day of the scheduled MRI, you must call the Research scanner room at 617-667-3361 to inform the MRI Research team, in addition to sending a cancellation email. While we understand that extenuating circumstances may occur, repeated failure to cancel more than 48 hours in advance may lead to penalties.

6. MRI Studies with Pregnant Patients:

All participants will be asked if they are pregnant on the MRI Safety Screening Form. While there are no proven risks of MRI to pregnant patients, participants that are known to be pregnant will not be scanned without specific IRB approval, as they are considered a vulnerable population. We will accept participant assurance that they are not pregnant, but if they are unsure we will accept a negative pregnancy test result if your IRB protocol allows for this. If it does not, we will be unable to scan your participant. For further information, please inquire about our policy on Pregnant Patients in MRI Research.

7. MRI Studies with Contrast Injection:

If your subjects will be receiving a contrast injection as part of their study, the study team will need to arrive at the MRI Suite with a contrast order form signed by the study's responsible physician. You will also need to bring a signed IV access order form to be used in the event that an IV nurse needs to be paged to assist with IV catheter placement. Subjects must have a creatinine blood test within 24 hours prior to the scheduled scan time in order to confirm it is safe for the subject to receive contrast. Testing at the MRI facility using a point-of-care creatinine test can be performed by MRI Research staff if no recent blood test results are available. This will be charged to the study's grant. If the subject has results from the within the last 24 hours, please bring a copy of the official results to the scan with you.

If the subject will need to have their creatinine tested on the day of the MRI, please state this in the initial scheduling email so a member of the MRI Research team will be available to run point-of-care creatinine testing.

If the subject receiving contrast is capable of bearing children, they will need to undergo a point-of-care pregnancy test on the day of the scan to ensure that it is safe for them to receive contrast. If the subject will require a pregnancy test, please state this in the initial scheduling email, so that a member of the MRI Research team can be made available to run point-of-care pregnancy testing. These tests will be charged to your study's grant. The Medical Safety Officer of MRI Research may also be consulted in the case of a positive test result.

If subjects will be receiving contrast for your study, the IRB protocol and consent form must include language outlining point-of-care creatinine and pregnancy testing. If this language is not included, your study team will need to file a deviation in order to run the necessary testing. Contrast will not be administered to the subject without an acceptable creatinine level and a negative pregnancy test result, if applicable (explained further in our POC Creatinine and POC Pregnancy policies).

8. Unexpected Findings:

We require that you include a procedure for handling suspicious findings in your IRB protocols. You can contact MRI Research for examples of language for incidental suspicious findings for your protocols.

9. Other Studies: If you are interested in scanning any studies, with or without a technologist, that do not fall under the categories above, such as phantoms, animals, specimens, etc., please contact MRIResearch@bidmc.harvard.edu. Certain studies may be eligible for a lower scanning rate.

For any animal studies which are carried out in a patient area or scanner, you may need to amend your study if you have not included transportation and handling in the MRI area. All studies must follow IACUC guidelines for infection control and clinical area plans.

