

MRI Research Facility COVID-19 Research Safety Plan and Justification

Overview

The Brown MRI Research Facility (MRF) is a **Core Research Facility** within the Division of Biology and Medicine and the Carney Institute for Brain Science that provides MRI scanning services to Brown affiliated researchers. The MRF occupies a 3,000 sq. ft. suite on the first floor of Sidney Frank Hall's west wing, and it has restricted card key access. The suite contains areas for participant waiting; a bathroom for changing and hand washing; a small procedure room adjacent to the waiting room; an animal prep area jointly managed by ACF; a control room, from which operators and researchers operate the MRI scanner, hereafter referred to as the "scanner," and the scanner room, which house the MRI system.

All research groups intending to use the MRF must have IRB (for human subject research) or IACUC (for vertebrate animal research) approval before their studies can commence. Additionally, the MRF's Scientific Advisory Committee reviews all potential research projects, involving humans, experimental animals or materials, for safety and feasibility, before a study can commence. Specific to Stage 2 resuming research procedures, we will require all research groups to document that they have received University approval to conduct research under the Stage 2 policy requirements and that they have read, understood and will abide by the MRF Stage 2 safety plan..

Description of Work to be Done

During Stage 2 of resuming research at Brown, research activities at the MRF include structural and functional scanning of the human brain and other body parts, as well as imaging of both awake and anesthetized experimental animals, with the main focus on central nervous system imaging. Some projects image materials, without any living specimens, or cell cultures. The MRF supports both basic science and clinical research studies. Human research participants range in age from pediatric to the elderly, with each project specifying the age-range. A variety of clinical research studies investigate a wide range of neuropsychiatric, neurodevelopmental and other disorders.

We expect that all those using the MRF during Stage 2 research resumption will have read, understood and will abide by the directives appearing in this document and any related material required by the University for resumption of research under Stage 2 procedures, and that they will have received University approval to conduct research under Stage 2 procedures.

Justification

This document describes the protocols proposed for conducting research in the MRF during Brown's Stage 2 reopening research process for work with human participants, experimental animals, cell cultures, and materials, as well as methods development by MRF staff. By their nature, MRI based procedures of the types conducted at the MRF *cannot be done remotely*.

The MRF supports mission-critical research. Much of the work done at the MRF supports development of clinical therapies and extended delays threaten the progress of this work. In addition, work at the MRF supports many early stage researchers, as defined in Principle #4 of the University's Principles and Procedures for Resuming Work in Research Facilities. In accordance with University guidance, we anticipate research at the MRF will ramp up in a staged fashion. The protocols outlined here are specific [to Stage 2, during which operations will be expanded beyond the limits of Stage 1 research, for which we received approval to conduct work with experimental animals](#). These procedures will be amended as restrictions are [modified](#) by the University and the State of RI and submitted to the University for approval.

Personnel

- Lynn Fanella, MRI Facility Manager
- Fabienne McEleney, MRI Research Specialist
- Michael Worden, MRF Associate Director of Research
- Edward Walsh, MRF Associate Director of Physics

The scanner will be operated primarily by Fanella and McEleney, who will work separate shifts, as needed. Associate Directors Worden and Walsh are both qualified to operate the scanner and will provide back up should either of the primary operators become unavailable.

Various researchers (including faculty, postdoctoral fellows and graduate students) have been trained and certified according to MRF procedures as "Level 3" scanner operators and will be permitted to scan independently during Stage 2 of resuming research at Brown.

Scanner Operators, either MRF staff or Level 3 certified researchers working in client laboratories will assume responsibility for implementing all Stage 2 related safety procedures, in addition to all standard MRI safety procedures.

Safety Plan

Individuals Working Alone. Scanner operators may be alone while waiting for researchers to arrive. Associate Director Worden will be designated as a point person and operators will communicate with him via text message when entering and leaving the facility. Dr. Worden may work alone to maintain research infrastructure and will communicate via text messages with Facility Manager Fanella and Director Sanes when doing so. Dr. Walsh may work alone to install and test imaging sequences on the scanner and will communicate via text messages with Dr. Worden and Ms. Fanella when doing so. If Michael Worden does not have availability to serve as the "point-person", then either Lynn Fanella and/or Jerome Sanes, the MRF Director, can receive and send text messages for those operating the MRI system.

Health Screening Protocol. Prior to entering the MRI suite for research purposes, all individuals must be screened for possible COVID-19 related symptoms, as prescribed in the Brown COVID-19 Workplace Safety Policy and updated as necessary according to CDC guidance. Symptomatic individuals are not permitted to enter the suite. Notices will be posted on the door of the suite indicating this restriction.

MRF staff (Level 3 Scanner Operator) will self-screen. If an operator experiences any symptoms consistent with COVID-19, the back-up Operator will be called in if feasible or the scanning session will be cancelled.

Level 3 Scanner Operators who are not MRF staff will be trained on all COVID-19 safety-related procedures appearing in this document, and they will each submit a signed attestation that they have read, understand and will abide by all current COVID-19 safety-related procedures related to MRI studies.

As new procedures become implemented, all Level 3 personnel (MRF staff and non-MRF staff) will receive instructions and, as needed, training to follow new guidelines.

Research staff conducting the study and the volunteer (and escort, as applicable) will be screened for COVID-19 symptoms at the time of arrival for their MRI scan by the Scanner Operator. This screening will occur immediately outside of the MRF Suite in the enclosed vestibule just inside the perimeter door to Sidney Frank Hall, first floor, administrative wing, therefore away from any potential foot traffic. The door from the vestibule to the 1st floor corridor will be prevented from opening during the screening. If the volunteer (and escort, as applicable) or any of the research staff exhibits any symptoms consistent with a COVID-19 infection, neither the research staff nor the volunteer (or escort, as applicable) will be permitted into the MRI suite and the scan will be cancelled. Additionally, research participants must be pre-screened by research staff conducting the study on the day prior to scanning for symptoms consistent with COVID-19. Specifically, volunteers must be asked if they are currently or have recently experienced any COVID-19 symptoms. If the volunteer reports any of these symptoms, the scan will be cancelled.

Site Occupancy and scheduling. Only the minimum number of individuals may be present in the MRF suite. Only one research group will be allowed in the MRF suite at any time.

- Research groups will be limited to one researcher and one research volunteer/participant. In cases for which the participant requires an escort (e.g., pediatric or elderly volunteers), only one escort will be allowed.

- Participants will be required to wait outside the building until called. Researchers will escort participants into the building via a building entrance directly adjacent to the MRF suite.
- The policy permitting only one researcher may will preclude some types of work, such as combined EEG/MRI studies, for which additional researchers are required for which prolonged close contact is required (e.g., application of electrode caps).
- Research groups can petition the University to conduct studies that require more than one researcher to have close contact to volunteers for more than 10-15 minutes. These procedures include combined EEG/MRI studies, a variety or non-invasive brain stimulation studies, among others. During Stage 2 or resuming research at Brown, the MRF will work with research groups and the University in accommodating such research.
- We expect that the researcher and the research volunteer (and escort, if applicable) will arrive for the research procedures with personal protective equipment (PPE), which minimally will require masks equivalent to disposable surgical masks. If we deemed the masks unsuitable, we will, as needed, issue disposable surgical masks to the research and volunteer (and escort if applicable). Before the volunteer enters the room containing the MRI system, we will require the volunteer to change from their mask to a disposable surgical masks, for which the Level 3 scanner Operator has removed the metal insert. The metal inset must be removed, since otherwise, it would cause distortions in the MR images.
- MRF staff will wear N95 masks during the short periods that they have close contact with research volunteers, during placement into and removal from the MRI bore. Otherwise, they will wear KN95 masks or disposable surgical masks when conducting other aspects of the MRI workflow (e.g., greeting the researcher and volunteer, conducting the scan in the Control Room, etc.). We have already determined that there is no need to remove the metal strips from any of these masks. The MRF will work with the Environmental Health and Safety group on the selection of suitable masks.
- The MRF is adjacent to the Leduc Imaging Facility, and it has been common for users of that facility to use the building entrance just outside the front door of the MRF suite and also for individuals to use that door and attached corridor as a cut-through to the BioMed Center and other areas of Sidney Frank. To limit density in the corridor, the building entrance adjacent to the MRF suite is now designated for MRI access only, as of June 29th, 2020 and card access to that door is restricted to those having been granted card access to the MRF Waiting area.

Although the overall MRF suite is approx. 3,000 sq ft. (cap. 10), it is divided into smaller functional areas and the nature of the work being done will require some exceptions to density guidelines. The entire suite is configured with single-pass ventilation with a high number of air changes per hour.

The Waiting Room (~350 sq ft) will be occupied by the researcher and the volunteer for purposes of MRI safety screening, instructions, and other preparatory research activities, before the participant is brought into the Scanner Room. In the event that the participant requires an escort, the escort will also occupy the waiting room. We expect that the escort will already be a close contact of the participant; regardless, escorts will also be screened for COVID-19 symptoms, as described above. The Waiting Room has an open layout that is conducive to social distancing. A six-foot long table will be located in the center of the room to allow the researcher to sit at one end and interact with the participant who will sit at the other end of the table.

The Scanner Room (~425 sq ft) will be occupied only by the participant during scan procedures. Positioning the subject for the scan requires the participation of both the Scanner Operator and the researcher, all of whom will be masked, at distances of less than six feet, for a brief period of time (1-3 minutes). Experimental animal research typically requires two individuals to position the animal for a time of approximately 3-5 minutes.

The Control Room (~160 sq ft) will be occupied by the Scanner Operator, at the MRI system console, and the researcher, who will operate research equipment (e.g., computers) and communicate via intercom with the participant. Escorts, if on-site, or other researchers, in the case of experimental animal studies, will not be permitted in the control room. On rare occasions, it may be necessary for a third individual (Worden or Walsh) to enter the control room briefly during scanning to troubleshoot research equipment or scanner protocol.

The Simulator Room (~250 sq ft) may be occupied by one researcher and one participant. This room is typically used for pediatric populations and one parent will also be allowed to accompany a child.

In order to limit time on-site, all non-scanning related procedures (e.g., interviews, post-scan testing, etc.) must be conducted off-site. The small procedure room will be closed. However, we will move the equipment currently housed in the small procedure room to a semi-isolated space toward the back of the Waiting Room, for the purposes of initial behavioral testing and other procedures, all of which will abide by the requirements of Stage 2 distancing.

All **scheduling** is currently done and will continue to be done by a moderated Google calendar. During Stage 2, we will require a **one-hour buffer between bookings** to allow for time for disinfection procedures and to ensure that only one research group (researcher and participant) is on-site at any one time.

Infection Control. All MRF staff, researchers, and volunteers will be required to wash hands or use hand sanitizer upon entry to the facility and upon exit. Note that MRF has a washroom adjacent to the waiting area (SFH 126) and we have installed a hand sanitizing station in the waiting area at the door to the control room (SFH 124A).

MRF staff will wear a lab coat and all staff, researchers and volunteers must wear masks or other face coverings at all times while on site. except when sitting alone in their single occupancy offices (Drs. Walsh and Worden) or alone in the multiple occupancy office spaces (Ms. Fanella and Ms. McEleney).

No food or drinks will be allowed in the control room.

A disposable chuck will be placed under the research participants head to create a barrier between the head and the immobilization pillows.

The scanner table, coil and any equipment in contact with subject will be wiped down before and after use with an approved disinfectant. These items will be disinfected with a hydrogen peroxide 0.5% product, which has an effective contact time of 30 seconds for use against the SARS-CoV-2 virus (<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19>; see EPA registration number 74559-9). We currently use the product Rescue but will be switching to Peroxiguard, an equivalent product. Disinfection protocols for animal scans will follow current IBC approved procedures. Keyboards, mice, and other research compute equipment in the control room will be wiped down with Lysol wipes, or their equivalent, after scanning as will the counter inside the MRF Control Room, which the scanner operator uses during scanning.

Linens for the scanner and MRI simulator will be changed between each participant.

Fabric covered chairs currently in waiting room have been replaced, in consultation with EH&S, with plastic and vinyl to facilitate disinfection. High touch surfaces will be wiped down by the scanner operator after each scanner session.

Contact Tracing. To facilitate contact tracing in the event of illness or exposure, the MRF will maintain a log book. All staff, researchers and volunteers will be logged with respect to time entering and leaving the Facility. If the researcher or the volunteer (or escort) declines to provide contact information, the scanning session will be cancelled before it begins. We will maintain contact information for 30 days in a secure location, whereupon the pieces of paper will be shredded and discarded.

Training. Safety and equipment training is an important component of MRF operations. While not part of the routine research studies, all researchers must undergo varying levels of MRI safety training, which we propose to continue during Stage 2 ramp-up, as time and staffing permit. Basic safety training (Level 1) is required for anyone to conduct research operations at the MRF, and it will be conducted individually in the Simulator Room. This training can be done independently by the trainee with a follow-up questionnaire. Level 2 training, which includes emergency procedures training, will be conducted individually in the Scanner Room by Fanella or by Worden, if Fanella is unavailable, and it will only occur during periods of no data collection. Level 3 (Scanner Operator) training will be

suspended during Stage 2. Level 1 and Level 2 training will both incorporate training on required infection control procedures.

Materials Research. The scanner may be also be used for materials research that does not require placing a human or experimental animals into the scanner. In such cases, MRF staff (generally Walsh or Fanella) will operate the scanner and research groups will be limited to having a single individual attend the scan session. The researcher may be present in the control room (with PPE as described above) for the purposes of consulting with the scanner operator on research parameters and image review but will otherwise remain outside the control room in the Waiting space. The scanner, control room and all research equipment will be disinfected as described above.

MRI Sequence Development. From time to time, it is necessary to scan a water bottle or human for the purpose of scan sequence or protocol development. In the case of involvement a human participant, this work is not considered human subjects research by Brown's IRB and generally relies on volunteers from research labs to be scanned (undergraduates are not permitted), who are required to sign an indemnification waiver developed by Brown's Office of General Counsel. This work will follow the same protocols outlined above for human subjects research with regard to social distancing and disinfection.

Equipment Development. MRF staff require access to MRF space to maintain equipment and to develop procedures used by the MRF user community. This work is most commonly done by Michael Worden, the Associate Director for Research, and it's done in solitude. As needed, Dr. Worden will coordinate with the other MRF staff and research groups to ensure that the work is done in a responsible manner, using proper social distancing.

Training of Research Assistants. Since staff of research groups has turnover, we anticipate a need for on-site training for newly arrived or newly re-assigned research staff from many of the research groups that use the MRF's facilities. In these cases, and during the Stage 2 period, the number of people permitted to participate in the research scan will increase by one, to three if the volunteer is accompanied only by the researcher or to four if the volunteer is also accompanied by an escort (e.g., a child or an adult with a medical condition requiring an escort, such as Alzheimer's disease). Thus, we would permit inclusion of only one additional individual and only for the purposes of training the person how a particular lab conducts their MRI-related research. We will require the lab PI to inform us in advance of such training and their expectation of how many sessions they expect will be needed to train the new research staff person. We will communicate with the PI about the progress of the training, and when it has finished, the lab will revert to the staffing plan of one researcher only, along with the volunteer, and escort, as needed. We will apply all the screening and distancing procedures detailed above for the trainee, who will essentially be considered an observer, though this person must abide by all Stage 2 practices described above.