York MRI Facility - Health and Safety Plan for Human Participant Research

Researcher information:

Applicant name: Diana Gorbet (MRI Facility Coordinator) **Principal Investigator name (if different):** Dale Stevens (MRI Facility Director)	**Area (Faculty/Department/Unit, Building):** MRI Facility (Faculty of Health, Sherman Health Science Research Centre)
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Research Location:

On campus? if yes then please provide:	
Room(s): MRI suite (MRI room, control room, behaviour assessment room, waiting room)	**Building(s):** Sherman Health Science Research Centre
Off campus? if yes then please answer the following:	
1. Will the research be undertaken in Ontario? please state location	N/A
2. Will the research be undertaken in another province? please state location	N/A
3. Will the research be undertaken in another country? please state location:	N/A

For research INSIDE Ontario:

Please outline, in as much detail as possible, the health and safety measures you will be taking with regards to the following items
NOTE: Health and safety measures must be specific to the corresponding step of the Reopening Act.

* Please note that the proposed Health and Safety plan described below does not vary depending on the current step of the provincial COVID-19 Reopening Act. The York MRI Facility is a shared space used by researchers both internal and external to the University. As such, the proposed restrictions and procedures detailed below aim to provide the highest level of health and safety measures possible for all users and staff of the Facility at all times.

COVID-19 Screening and incident management (for faculty, staff, students)

The MRI Facility will follow the procedures for COVID-19 screening and incident management outlined on York University's website: https://www.yorku.ca/bettertogether/wp-content/uploads/sites/299/2021/08/09.08.2021-Self-Disclosure-Screening-and-Incident-Management-Protocol.pdf

All potential visitors to the MRI Facility must be provided with a link to the YU-Screen website: https://yorku.ubixhealth.com/login. Potential visitors must be instructed to use this website to screen for COVID-19 and to verify their vaccination status prior to coming to campus. Any individual who does not clear YU-Screen must not come to campus.

To facilitate contact tracing if required, an MRI Facility staff member will collect the full name, email address, and phone number of any visitors to the facility (i.e., researchers, study participants, and caregivers). The staff member will also record the date, arrival time, and departure time of each visitor. This information will be kept confidential and stored in a locked cabinet within the MRI Facility.

Hand hygiene and respiratory etiquette, use of masks or face coverings, Personal Protective Equipment (PPE)

A hand sanitizer station will be set up within the MRI suite. Hand sanitizer dispensers and the soap dispenser in the MRI suite washroom will be checked regularly to ensure they are refilled when required. Researchers, participants, and caregivers will be expected to use hand sanitizer immediately upon entering the MRI Suite. The technologist will sanitize and/or wash their hands before and after all contact with research participants.

Researchers, participants, and caregivers will be provided with level 2 (or higher) surgical masks and will be expected to don masks prior to entry into the MRI Facility and wear these masks at all times while in the Facility. The provided level 2 surgical masks must cover the nose, mouth, and chin. Researchers and caregivers may wear the provided mask on top of or instead of masks that they may have brought with them or are already wearing. Participants going into the MRI will be required to wear only the mask provided to them to ensure MRI-compatibility.

Following recent safety recommendations, masks for research participants who will be undergoing MRI scanning will be metal free (https://www.fda.gov/medical-devices/safety-communications/wear-face-masks-no-metal-during-mri-exams-fda-safety-communication). Masks that have been tested for use in the MRI scanner will be supplied to study participants, if available (e.g., https://www.newmaticmedical.com/product/MRI-Safe-USA-Made-Surgical-Mask-ML-NM110836). However, there are very few masks available for purchase that have been tested in MRI systems. Therefore, following recommended MR safety procedures, if certified MRI safe masks are not available, participants will be provided with standard level 2 (or higher) surgical masks which do not have metallic staples and from which the metal nose piece has been removed (https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety/COVID-19-and-MR-Use). If needed (i.e., a gap is present at the bridge of the nose), a piece of hypoallergenic medical grade tape will be used at the bridge of the nose to provide a better seal to the participant's face. Prior to using these masks with participants, we will also test them in

the MRI scanner during commonly performed scanning protocols to verify that they do not contain metallic fibres or coatings and are safe for participants within the MRI.

In some cases, having a participant wear a mask in the MRI might have a negative impact on an experimental setup. For example, the mask might partially obstruct vision of experimental stimuli presented from some angles. If possible, the researcher should adjust the experimental setup to accommodate having the participant wear a mask. If it is not possible to adjust the experimental setup to allow the participant to wear a mask, the participant may remove their mask from within the MRI room for the duration of the MRI scan. The participant should continue wearing a mask at all other times during the experiment. **If it is necessary for the participant to remove their mask during an experimental session, the researcher must maintain documented verification (e.g. a screenshot) that the participant cleared their covid screening (via YU Screen) and is vaccinated.**

In addition to a level 2 (or higher) surgical mask, the MRI technologist will also wear either a face shield or goggles. The technologist will wear nitrile gloves when setting up participants in the MRI scanner. Gloves will be discarded after each use, followed by hand sanitizing.

Cleaning and disinfecting

Scheduling of MRI scanning sessions will include 15 minutes between sessions to allow for disinfection of any surface that may have come into contact with a visitor to the Facility. Researchers/participants who have arrived for a scanning session will not be allowed into the Facility until the previous researcher and participant have left and disinfection has been completed.

Fresh linen will be used on the MRI scanner bed for each participant. Linen includes a sheet over the MRI bed and a pillowcase placed over the head cradle in which the participant's head rests. Linen will be changed after each participant and placed in a sealed container for professional cleaning by the linen cleaning service used by the MRI Facility (Faster Linen - https://www.fasterlinen.com/).

Surfaces such as tables and workstations in the MRI Facility will be kept free of unnecessary objects and clutter to facilitate cleaning. A cleaning checklist will be used to make sure that any surface that visitors to the Facility might contact is disinfected after each scanning session, including:

- MRI bore
- MRI coils
- MRI bed
- MRI padding (only padding with a wipeable, vinyl surface will be used)
- MRI emergency squeeze ball
- MRI eye tracker (if used in experiment)
- MRI projection screens (if used in experiment)
- MRI button pads (if used in experiment)
- Door handles
- Chairs
- Shared computer keyboards and mice
- Tables
- Shared pens

Disinfection of surfaces will be performed using a product approved for use by Health Canada against the SARS-CoV-2 (COVID-19) virus (https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/list.html). Disinfection using approved products will adhere to the manufacturer instructions found on product labels. As recommended by Public Health Ontario Infection Prevention and Control guidelines, cleaning will be performed from "high to low" areas to avoid microorganisms dripping down and re-contaminating areas that have already been cleaned. Disposable gloves will be worn during cleaning and hand sanitization will be performed before and after cleaning (https://www.publichealthontario.ca/-/media/documents/B/2018/bp-environmental-cleaning.pdf). In addition to disinfection performed by MRI Facility staff after each scanning session, we will request that York Facilities increase the frequency of cleaning of the MRI Facility, including high-touch surfaces such as doorknobs and the in-suite washroom in particular.

Physical distancing

The MRI scanning area within the MRI Facility consists of an outer control room and an inner MRI scanner room. The control room houses computer systems that control the MRI scanner and all associated equipment. The MRI room contains the MRI scanner and is accessed via the control room.

For most of the time spent in the MRI Facility, all visitors will be required to maintain at least 2 metres of physical distance from other people. However, some contact between the MRI Technologist and the study participant is unavoidable when the Technologist positions the participant on the MRI scanner bed prior to scanning. For example, the Technologist may place padding between the participant's head and the MRI head-coil system used for data collection during brain scans. Similarly, depending on the nature of the research being conducted, the Technologist may be required to place equipment on or around the participant such as projection screens for viewing visual stimuli or eye tracking equipment for monitoring eye position during experiments. The MRI Technologist leaves the MRI scanner room after set-up is complete and prior to initialization of MRI scans (control of the MRI system occurs from the control room immediately outside of the MRI scanner room). The amount of time the Technologist spends in the MRI room at a distance of less than 2 metres from the participant will be minimized as much as possible.

During MRI experiments, a Researcher usually must be present in the MRI control room with the MRI Technologist (e.g., to control visual stimuli viewed by participants and/or to monitor/record participant responses, etc.). The Researcher will work at a workstation that is situated at least 2 metres away from where the Technologist is required to sit to control the MRI. Both the Researcher and the Technologist will continue to wear a Level 2 mask at all times when in the facility.

Within the MRI Facility, there is also an assessment room outside of the main MRI scanning area used for collection of behavioural data, questionnaire information, etc. A limit of one researcher and one participant (and caregiver, if present and required) will be allowed to occupy this space with a minimum of 2 metres of distance between the Researcher and the participant (and caregiver, if present and required).

Shared spaces (e.g., equipment, vehicles, common work areas)

The MRI Facility and all the equipment within it are shared. The procedures described in this document for COVID-19 screening, hand hygiene and respiratory etiquette, cleaning and disinfecting, physical distancing, use of masks/face coverings/PPE, and capacity limits all take the shared nature of the MRI space/equipment into account.

Capacity Limits

Within the MRI control and scanner rooms, there will be no more than one researcher, one study participant, and one technologist at any given time. One caregiver, if required (e.g., if the study participant is a child, older adult, or anyone needing assistance), may also be admitted to the MRI Facility after COVID-19 screening. The caregiver will wait outside of the MRI control room in the MRI suite's waiting room for the duration of the session.

The MRI suite also contains a room for the administration of behavioural assessments. If needed, the researcher and the participant (accompanied by caregiver, if present and required) will be allowed to use this space with at least 2 metres of distancing between the Researcher and the participant (and caregiver, if present and required), if possible.

We expect that the capacity limits detailed above will be followed in the vast majority of studies undertaken at the York MRI Facility. In rare cases, a study may unavoidably require the presence of additional research staff and/or participants above the limits specified above. Where the presence of additional people is required by a study, the staff of the York MRI Facility will work with York Health and Safety to make sure that safe procedures and restrictions are outlined, approved, and followed in these exceptional cases.

Other additional measures, specific to your areas (e.g., capacity)

Requests for MRI scan time will only be granted to researchers whose projects have received prior Health and Safety approval by the University.

A link to the York COVID-19 screening tool will be added to the MRI Facility's website and will be provided to potential visitors to the MRI Facility via email upon confirmation of scan booking.

The usual MRI Facility fees for cancellation of a scheduled scanning session occurring less than 24 hours ahead of time will be waved in the event that a researcher or participant discloses that they may have COVID-19 symptoms or may have come into contact with a confirmed or probable COVID-19 case, resulting in the cancelation of a scheduled MRI scan.

The most up-to-date version of the York MRI Facility's Health and Safety Plan will be posted on the York MRI Facility website (https://mri.info.yorku.ca/york-mri-facility-covid-19-update/).