RESEARCH 3.0T MR
CONSENT FORM

Rotman Research Institute
Baycrest Health Sciences
3560 Bathurst Street, Toronto, ON M6A 2E1

Title of project:

Principal Investigator:

Co-Investigators:

COVID – 19

- The Baycrest Research site is located under the jurisdiction of Ontario public health guidelines. We are taking all safety precautions to reduce the risk of spread of COVID-19 and expect you to follow public health directives as well.

- If you feel that you are from a vulnerable group with respect to COVID-19 effects (e.g., senior, immuno-compromised), please discuss your participation with the research team before consenting. You are under no obligation to participate and nothing bad will happen if you change your mind about participating in the research.

- Because you are coming onto the Baycrest campus, the following safety protocols must be followed, as per Occupational Health and Safety guidelines:
    - Screening – as per requirements for persons coming onsite.
    - Take appropriate precautions (e.g. face covering / cloth mask) if taking public transportation and entering public indoor spaces.
    - Wash your hands upon coming onto campus / entrance to building. Hand sanitizer will be made available to you.
    - Universal masking at all times on site at Baycrest.

- We will be collecting personal contact information that we must retain in order to follow up with you and/or conduct contact tracing if you may have been exposed to COVID-19 in coming to Baycrest.

- Contact information will be kept separate from data collected through the research study to allow for de-identification of the research data (if applicable, as detailed in the protocol).

- You maintain your right to withdraw from the study at any time, including research data (if applicable). If you do withdraw, we will continue to maintain your contact information and will only give it to Occupational Health & Safety if required for contact tracing.

- We cannot guarantee anonymity as the personal contact information identifies you as a participant.

Nature and the Purpose of this Study

MRI Scan

The MRI scan will be conducted at Baycrest. The MRI technique uses magnets and radio waves to construct a picture of the brain on a computer. MRI does not involve radiation (i.e., ionizing radiation) used for an x-ray or computed tomography (CT) scan. Before the scan begins, you will be asked to remove any metallic items that you may be wearing. You will be provided with a hospital gown and PJ bottoms to change into. A locker will be provided to secure your belongings. For the procedure, you will be asked to lie on a padded bed that will be moved into a tunnel-like machine for the MRI scan of your brain. Since you will be inside the machine during the scan, and a screen will be in place for viewing the visual images, you may not be able to see the MRI technologists operating the machine or the investigators. However, there is an intercom system that will allow you to talk with them at any time. If you feel uncomfortable during the scan and you wish to discontinue the procedure, you will be taken out of the machine at your request.

We will obtain a series of MRI scans, separated by short breaks, and the entire procedure will take approximately **X** hours. The machine will be quite noisy during the scan. To reduce the noise, you will be given earplugs and or headphones. During the scans we may ask you to carry out a variety of tasks. You should try to remain as still as possible during each scan. Movement will not be dangerous to you in any way, but would blur the picture of your brain. You will hear moderately loud knocking or beeping during the scan when the MRI machine is in operation.

Tasks

Risks of an MRI scan

The MRI scan is not associated with any known risks to your health and there is no evidence that there will be either short-term or long-term side effects. MRI does not involve radiation (i.e., ionizing radiation) used for an x-ray or computed tomography (CT) scan. However, it is our policy that if you are a woman of child-bearing age, that you not be pregnant at the time of the MRI scan. Prior to the MRI you will be required to fill out a questionnaire to ensure that there are no contraindications for performing the study. The only absolute requirements for the MRI scan are that you

1) Do NOT have an implanted cardiac pacemaker
2) Do NOT have any metal implants, pieces of shrapnel, aneurysm clips, or wires in your head.
3) Do not suffer from claustrophobia.

If you are a woman of child-bearing age, it is best that you are not pregnant at the time of the MRI scan. If you have a tattoo, there is a very small possibility that you will feel a tingling or burning sensation at the tattoo site.

Participation in the Study

Your participation is voluntary. You may refuse to participate in the study at any point in time. The study will not benefit you specifically, but knowledge will be gained that may benefit others. If any new information about risks or benefits of MRI are obtained you will be informed. Each individual's results are confidential. We may request your permission to access your medical records to obtain background information (for example, previous MRI or CT scans, or results of neurological or neuropsychological exams) relevant to the study. This information will remain confidential and will only be accessible to the investigators during the course of the study. Neither your identity nor any personal information will be available to anyone other than the investigators. No personal information will be disclosed in any resulting publication or presentation. If you are interested, we would be happy to provide you with the final results of the study when they appear in press. I understand that my imaging data will be stored indefinitely and that the data will be made anonymous in that my identity will not be stored with the image data. Only coded identifiers will be kept with the imaging data and the link between that coded identifier and my identity will be kept in another secure and confidential location separate from the images.

I understand that research carried out using my imaging data by researchers at Baycrest, or their collaborators, may lead to the development of marketable treatments, devices, new drugs or patentable procedures. However, I understand that I will not be entitled to any benefits derived from any such commercial developments and that any benefit from commercial products will remain with Baycrest and its research partners.

I understand that I am voluntarily providing my imaging data for research purposes. I further understand that I may withdraw my consent to have my imaging data used for research purposes at any time in the future by contacting the Research Ethics Board at Baycrest.

The MRI scan being done is designed to answer research questions, not to examine your brain medically. This MRI scan is not a substitute for one that a doctor would order, and it may not show problems that would be picked up by a medical MRI scan. However, in the unlikely event that we note an atypical finding on your MRI scan, we will contact you to help you arrange medical follow-up to interpret the significance of the findings, if any. We may also ask a radiologist, or other health professional, to look at your scan, and by signing this consent form you agree to releasing the scan for review. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

If you have any questions, please contact xxx at (416) 785-2500, ext. **XXXX** or by fax at (416) 785-2862.

If you wish to contact someone not connected with the project about your rights as a research participant, feel free to call Dr. Daphne Maurer, Chair of the Research Ethics Board at (416) 785-2500 ext. 2440.

Signature Section

I have read the attached information form, and I understand the purpose of my participation, the procedures involved and the potential risks to myself, as stated in this document. All my questions have been answered to my satisfaction. I understand that I can ask further questions during any stage of the study.

I understand that my participation in the study is voluntary. I may withdraw from the study at any point in time. I am aware that the study will not benefit me specifically, but knowledge will be gained that will benefit others. It has been explained to me that the results of the study are confidential. Neither my identity nor any personal information will be available to anyone other than the investigators. No personal information will be disclosed in any resulting publication or presentation. I have been informed that I will be notified if any unexpected findings are noted on my MRI scans. I have been given a copy of this consent form. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.

I will be reimbursed $50XXX for the time of my participation and for travel expenses.

If I am a woman of child-bearing age, I confirm that I am not or could not be pregnant at the time of the MRI scan.

The study and its consequences have been explained to me by: _____.

If I have any further questions I may call xxxx at 785-2500 ext. xxxx

_____

Name of Participant / Substitute Decision-Maker Signature Date

Relationship to Participant_____

Signature of Person Obtaining Consent

I have personally explained the research to the patient or his/her legally authorized representative and answered all of his/her questions. I believe that she/he understands the information described in this document and freely consents to participate.

_____

Name of Person Obtaining Informed Consent Signature Date