

CLSA COVID-19 Brain Study PARTICIPANT INFORMATION SHEET

As a longstanding participant in the Canadian Longitudinal Study on Aging (CLSA), we are inviting you to participate in the CLSA COVID-19 Brain Study, a study in which we ask you to:

- 1) Complete one short telephone interview; and,
- 2) Come into a clinic to get a magnetic resonance image (MRI) taken of your brain. If you experience claustrophobia, you should not take part in this study.

You **will be** asked to repeat the MRI and the short telephone interview in two years (i.e., 2022/2023) and in addition, you **may be** invited to repeat the MRI and short telephone interview in the next 12 months. These MRIs and other data will become part of the CLSA dataset and will allow researchers to specifically look at the direct and indirect effects of COVID-19 on the brain.

We are collecting MRIs on a subset of CLSA participants so that we can compare the brain images of participants who have had, or are suspected to have had, COVID-19 to those who have not. All of this information is being collected to understand the short and long-term impact of COVID-19 on the brain.

This substudy of the CLSA is being funded by the Canadian Institutes of Health Research (CIHR) and a grant from the Weston Foundation. The study is being led by a team of researchers from across Canada including Dr. Teresa Liu-Ambrose (University of British Columbia), Dr. Eric Smith (University of Calgary) and Parminder Raina (McMaster University).

You should not take part in this study if:

- You have any of the following items implanted in your body:
 - Cardiac pacemaker, wires, or defibrillator
 - Metal fragment in the eye or orbit
 - Brain aneurysm clip
 - **Stainless steel** Intrauterine Device (IUD)
 - Artificial heart valve
 - Eye or ear implant
 - Implanted drug infusion pump
 - Electrical stimulator for nerves or bones
 - Coil, catheter or filter in any blood vessel
 - Orthopedic hardware (artificial joint, plate, screws, rods)
 - Other metallic prosthesis
 - Shrapnel, bullets, or other metallic fragments
 - Stent
 - Shunt
- You are pregnant;
- A doctor has ever told you that you have experienced a Stroke or CVA (Cerebrovascular accident);
- A doctor has ever told you that you have experienced a ministroke or TIA (Transient Ischemic Attack).

Please know that you can always contact us with any questions by emailing us at cogmob.research@hiphealth.ca or by telephone at 1-866-999-8303.

The CLSA COVID-19 Brain Study is being led by Dr. Teresa Liu-Ambrose (University of British Columbia), Dr. Eric Smith (University of Calgary) and Dr. Parminder Raina (McMaster University). The Brain Study also involves many researchers from universities across Canada. The overarching goal of the CLSA COVID-19 Brain Study is to permit better understanding about how COVID-19 affects our cognition and the brain both immediately and in the longer term. The Brain Study involves completing a phone interview regarding your cognition, feelings, and lifestyle. It also involves having magnetic resonance images (MRIs) done at a local clinic.

Analysing MRIs and accompanying data collected from participants will allow us to determine the effect of COVID-19 on human cognition and brain health.

Here is what you can expect to happen if you agree to participate in the CLSA-COVID-19 Brain Study:

- You will be contacted by CLSA staff to schedule the **telephone interview** and book a **1 hour MRI** appointment at a clinic associated with the CLSA data collection site (DCS) nearest to you. The MRI appointment will take place during regular business hours.
- Within approximately four weeks of the MRI visit, you will be called by a CLSA interviewer to complete a **telephone interview** that will take approximately 45 minutes.
The MRI appointment will also involve the following:
 - One week before your scheduled MRI appointment, CLSA staff will call to confirm your appointment and review some specific questions that are required by the MRI clinic to ensure it is safe to have an MRI done (similar to the questions we asked here, but specific to that clinic). During that call, staff will also ask you some questions to determine if you have any COVID-19 related symptoms or have been in contact with anyone with COVID-19 symptoms. We refer to these questions as “screening” questions.
 - If you have any COVID-19 related symptoms or have been in contact with someone who may have been exposed to the virus that causes COVID-19, we will reschedule your appointment to a time at least two weeks after this call.
 - If you do not have any symptoms and have not been in contact with someone who may have been exposed to the virus, then you will be asked to complete a short questionnaire that is similar to the questions we reviewed here about any physical or health reasons why the clinic would not be able to safely take an MRI. We ask these questions to ensure that you can go to get the scan.
- When your MRI appointment is confirmed, staff will also review any directions and protocols that are required by the clinic where you will go for your scan. All proper COVID-19 protocols will be followed, and this will also be reviewed when your appointment is booked.
- The day before your appointment, the CLSA will contact you to review the screening questions for COVID symptoms and exposure.

- The day of your appointment, the MRI clinic will also review the screening questions for MRI safety and COVID symptoms and exposure, according to their own protocols.

We **may** contact you again in approximately 1 year to arrange for a second interview and MRI, which will include the same process as described above. The second interview and MRI will only occur in a subset of the participants of the COVID-19 Brain Study. One year after that (two years following the first interview and MRI), another interview, and another MRI **will be** arranged.

It is important to note that the results from this study will not be available to you. The images and other data for this study are being collected for research purposes only.

There are some risks in providing an MRI:

- The magnetic effect of the MRI on implanted devices. The MRI could cause any metal in your body to heat up. This is because the MRI machine uses strong magnets to take pictures. Every effort will be made to eliminate this risk, by asking you ahead of time about any devices or injuries from metal objects, and not running the test if you have anything in your body that will be affected by the machine.
- There will be some discomfort caused by having to lie still and hear the noise from the scanner for the duration of the procedure. We will mitigate this discomfort in the following ways:
 - Headphones and ear plugs will be worn for ear protection.
 - Tingling sensations sometimes occur in the arms, but these can usually be prevented by keeping the hands apart.
 - We will maintain visual and verbal contact with you throughout the MRI scanning sessions.
 - As an extra precaution, you will be given an “emergency” button to be used if you wish to end the procedure.

There are also some COVID-19-related risks:

- COVID-19 is a respiratory illness primary spread through respiratory droplets, mainly from person-to-person contact. It is also possible that it can be spread by touching a surface or object that has the virus on it, and then touching your nose, mouth, or eyes.
- It must be noted that while for most people COVID-19 causes only mild or moderate symptoms, such as fever and cough, for some it can cause more serious illness, including pneumonia. Those at higher risk include older adults (those over 60) and people with chronic conditions such as cancer, diabetes and lung disease.
- It is important to understand that since participation in the CLSA COVID-19 Brain Study will require travel outside your home and increased exposure to others it may increase your exposure to COVID-19.
- The local MRI clinics follow established protocols for working safety during the pandemic and include maintaining physical distance of 2 metres whenever possible and use of appropriate personal protective equipment.

- As much of the data collection as can be done by phone rather than in person, will be collected from our participants that way. This is done to make the in-person appointment as short in length as possible.
- The information related to the risks of COVID-19 changes every day, and the minimization strategies that are most effective are also adjusted to meet these changes.

There are no direct benefits to you for participating in the study:

- Your participation in the CLSA COVID-19 Brain Study will contribute to increasing our understanding of the effects of COVID-19 on cognitive and neural health. A better understanding is critical to the identification of those at risk and timely deployment of therapeutic approaches to mitigate the cognitive and neural consequences of the COVID-19 pandemic.
- Your participation in this research study will not involve any costs to you except the time that it takes you to take part completing the MRI appointment. You will be given \$30 at your visit to put toward expenses such as parking or other travel related expenses.

Some final important information about the CLSA-COVID-19 Brain Study:

- Your agreement to participate in the CLSA COVID-19 Brain Study is entirely voluntary.
- Your decision to participate in the CLSA COVID-19 Brain Study does not affect your participation in the CLSA study that you have participated since 2012-2015.
- The MRI scan being done is designed to answer research questions, not examine your brain medically. This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. However, if we believe that we have found a medical problem in your MRI scan, we will contact you and with your permission, contact your family physician and help him or her get the right follow-up for you. No information generated in this study will become part of your record routinely. However, if the study detects an abnormality in your MRI scan and further follow-up is required, then this information may become part of your record.
- If you initially agree to participate in the CLSA COVID-19 Brain Study, you can change your mind at any time by contacting us.

By email
cogmob.research@hiphealth.ca

By telephone
1-866-999-8303

- If you have any questions about the CLSA COVID Brain Study, please contact us using the information provided above.

We will protect all the data you provide to us:

- When you consented to participate in the CLSA (2012-2015) you were given information about how the CLSA will protect any data and/ or samples collected. The CLSA-COVID-19 Brain Study is a sub study of the CLSA, as such all previous data collection processes that you agreed to as part of the CLSA apply to the CLSA COVID-19 Brain Study. The CLSA will protect any information and images collected as part of the CLSA COVID-19 Brain Study as we do for all CLSA participant information.
- The data collected as part of the CLSA-COVID-19 Brain Study will be shared for research purposes as per CLSA data sharing policies. You can read this information on the CLSA website at <https://www.clsa-elcv.ca/participants/information-documents> or request a copy of this information by contacting us by email at **info@clsa-elcv.ca** or telephone at **1-866-999-8303**.
- Every effort will be made to keep the information you provide private, but risk of accidental disclosure is possible.
- If you have any questions regarding your rights as a research participant, you may contact the Research Ethics Board associated with your Data Collection Site:

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