

CLSA COVID-19 Antibody Study: Venous Blood Draw 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 Antibody Study, a study in which we ask you to provide blood samples to determine the presence of antibodies and other markers responsible for COVID-19 and immunity, in your blood. This collection of samples will occur at a visit to the data collection site (DCS). This visit would be in addition to the regular DCS visits.

Antibody and immunity testing involves analysing blood samples to determine if a person has been infected with the virus that causes COVID-19. The blood samples we are collecting for antibody testing and markers of immunity, along with the data being collected from questionnaires related to COVID-19, will expand the CLSA's current data set and allow researchers to answer questions to inform COVID-19 prevention and control strategies. You are eligible to participate whether or not you have completed questionnaires as part of the CLSA-COVID-19 Study.

We are able to collect additional blood samples from CLSA participants through a partnership with the Government of Canada's COVID-19 Immunity Task Force (www.covid19immunitytaskforce.ca). The mandate of this task force is to describe the scope of coronavirus infection in Canada.

The CLSA COVID-19 Antibody Study is led by Dr. Parminder Raina from McMaster University and involves many researchers from universities across Canada. The overarching goal of the CLSA COVID-19 Antibody Study is to permit better understanding about how widespread COVID-19 infection is in Canada among older adults by looking at the presence of antibodies in the blood. The antibody testing involves collecting blood samples at two time points (six months apart) over the next 12 months.

Analysing blood samples collected from participants will allow us to determine if you have developed antibodies to the virus that causes COVID-19. The presence of antibodies in the blood means that you have been infected by the virus at some time in the past, even though you may not have been aware of this infection or experienced any symptoms.

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

- You will be contacted by CLSA staff to schedule a visit for blood sample collection at your local Data Collection Site.
- The day before your scheduled visit, CLSA staff will call to confirm your appointment and 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. We will also ask you a few questions to ensure you are able to provide a blood sample the next day.

- 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 includes demographic information, and we will also review the same questions we did today about any physical or health reasons why we would not be able to safely take a blood sample.
- When you arrive for your blood draw visit, you will be screened again for COVID-19. You will be required to disinfect your hands and wear a face mask, which will be provided to you.
- During your visit, you will be asked to provide about 50 mL of blood (about 3 tablespoons).
- CLSA staff will follow the COVID-19 safety protocols as required by their institution and local public health authority. This will include maintaining a distance of 2 metres whenever possible and wearing appropriate personal protective equipment during your visit. All CLSA staff will be required to wear a face mask, and staff taking blood will also be required to wear gloves, a gown and a face shield. All CLSA staff will undergo COVID-19 screening each day before entering the Data Collection Site. All these precautions are being taken to ensure your safety and the safety of CLSA staff.

We may contact you again in approximately six months to arrange for a second blood draw, which will include the same process as described above. The second blood draw is contingent on how widespread the infection is based on the results of the first blood draw. If the spread of the infection is extremely low, then we may not proceed with collection of the blood samples in six months.

It is important to note that the testing used to detect antibodies for the COVID-19 virus is not a diagnostic test to determine if you are currently infected and has no clinical meaning for you or your doctor. If test results show that you do have antibodies, then you were likely infected with this virus **at some time in the past** and may or may not have some immunity. It is currently not known whether the presence of antibodies means you are protected against reinfection. The level of immunity and how long immunity lasts are not yet known.

Results of the antibody test will be made available to you by email or mail following a review and interpretation of all of the study data with public health experts. Test results will be accompanied by information to help you understand what they mean. COVID-19 antibody testing detects the presence of antibodies made in response to COVID-19 infection. A positive result tells you about an infection that happened in the past but will not tell you if you are currently infected. These results will not be available for at least 3 months after the sample is provided.

There are some risks in providing a blood sample:

- Providing a blood sample for the CLSA COVID-19 Antibody Study presents the same risks as providing a blood sample during your regular CLSA visit.
- You may feel mild “pinprick” pain from the needle and/or have a small bruise on your arm. Some people may also feel dizzy. Although very rare, infection may occur
- Every effort will be made to prevent these risks.

There are also some COVID-19-related risks:

- COVID-19 is a respiratory illness primarily 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 Antibody Study will require travel outside your home and increased exposure to others it may increase your exposure to COVID-19.
- In order to minimize the risk to our participants and our staff, the CLSA requires that masks be worn by both staff and participants while in the data collection site, and that physical distancing (2 metres) be maintained whenever possible. In addition, all surfaces will be cleaned according to established protocols before and after each participant’s appointment.
- We are limiting the number of staff and participants allowed within the data collection site at one time. As much as possible data collection will be done by phone rather than in person. This is done to make the data collection site visit as short in length as possible.
- The information related to the risks of COVID-19 changes every day, and the mitigation strategies that are most effective are also adjusted to meet these changes. The CLSA will keep up-to-date on the recommendations and will alter protocols quickly to continue to meet those changes.

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

- Your participation in the CLSA COVID-19 Antibody Study will contribute to increasing our understanding of the virus that causes COVID-19 and will help inform public health prevention and control strategies for future outbreaks of this infection.

- Your participation in this research study will not involve any costs to you except the time that it takes you to take part in the study. 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 Antibody Study:

- Your agreement to participate in the CLSA COVID-19 Antibody Study is entirely voluntary.
- Your decision to participate in the CLSA COVID-19 Antibody Study does not affect your participation in the CLSA study that you have participated since 2012-2015.
- If you initially agree to participate in the CLSA COVID-19 Antibody Study, you can change your mind at any time by contacting us by email at info@clsa-elcv.ca or telephone at 1-866-999-8303.

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 Antibody Study is a sub study of the CLSA, as such all previous data and blood collection processes that you agreed to as part of the CLSA apply to the CLSA COVID-19 Antibody Study. The CLSA will protect any information and blood samples collected as part of the CLSA COVID-19 Antibody Study as we do for all CLSA participant information and samples.
- The data collected as part of the CLSA-COVID-19 Antibody 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.

COVID-19-specific limits on confidentiality:

- In the event that the CLSA becomes aware that a staff member or a participant tests positive for COVID-19, the local DCS will comply with any local public health measures for managing the pandemic such as contact tracing. This may require sharing your contact information (name and telephone number) to contact tracers to ensure that you are informed of the possible exposure.
- Your contact information is stored in a secure database for the purposes of contacting you for interviews and follow-up. Your research data are de-identified and stored in a separate database.

If you have any questions:

- For questions about the study please contact the CLSA Information Line at 1-866-999-8303 or info@clsa-elcv.ca.
- 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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