

Have you been vaccinated against COVID-19?

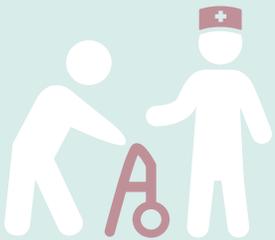
Do you have a history of COVID-19?

Do you want to know if you have immunity against COVID-19?



Help us help you

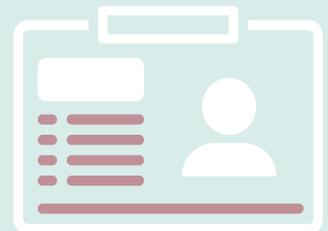
better understand what your personalized immunity profile against COVID-19 looks like



If you are a resident or worker in an LTC home, whether you have been vaccinated or not, you can participate in our study.



We will be safely collecting blood samples through a finger prick from you, at several timepoints, over the next 12 months.



We will measure whether you have antibodies against COVID-19 and share your personalized results with you.

Residents,

Please complete this 15 minutes survey in the link found in the QR code or enter the URL below:



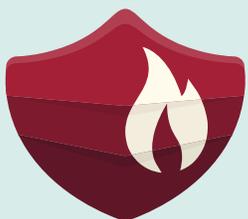
www.surveymonkey.ca/r/LTC-Residents-Immunity-Study

LTC Workers,

Please complete this 15 minutes survey in the link found in the QR code or enter the URL below:



www.surveymonkey.ca/r/LTC-Workers-Immunity-Study



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In collaboration with



To find out more about the Bruyère C19 Immunity Study and how to participate, please visit our webpage at

www.c19immunitystudy.ca

or send us an email at

c19immunitystudy@bruyere.org

Identification of underlying factors influencing the immune response to SARS-CoV-2 among workers and residents in long-term care homes: a multi-province study

You are being invited to participate in this study because you are a member of a long-term care facility, one of the most at-risk sub-populations during the pandemic. This information sheet will help you make an informed choice regarding your participation in this research. All your questions should be answered to your satisfaction before you decide whether you want to participate in the study.

Please take your time with this decision.

What is this study about?

This study is led by Dr. Amy Hsu from the Bruyère Research Institute and Professor Marc-André Langlois at the University of Ottawa, and involves many researchers from universities across Canada. The goal of this study is to build a better understanding about how widespread COVID-19 is in Canada among our most vulnerable and high-risk populations.

What do I have to do?

The research team is hoping to collect dried blood spot samples from you to look for the presence of antibodies against COVID-19.

You will be provided a testing kit that includes detailed information about how to self-collect a blood sample. Briefly, the process requires you to prick a finger, allow a blood drop to form, and then apply the drop of blood to a device (also known as a dried blood spot card) that has a special paper. Once the blood sample has been collected and allowed to dry, your dried blood spot card should be sent back to the research team for analysis via a pre-paid envelope that will accompany each test kit. We expect that the dried blood spot sample collection will take about 10 minutes to complete.

You will also be asked to complete a 15-minute questionnaire on SurveyMonkey.



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Over the next 12 months, the researchers will ask you to provide 3 to 4 additional samples, depending on whether you have received a COVID-19 vaccine.

Study Participant Type	Data Collection Schedule
If you are a Long-Term Care Worker who <u>has not received</u> a COVID-19 vaccine...	Your first data collection will include one blood sample and a completed questionnaire. After this, you will be tested 3 more times and provide a blood sample once every 3 months.
If you are a Long-Term Care Worker who <u>has received</u> a COVID-19 vaccine...	<p>Your first data collection will include one blood sample and a completed questionnaire. After this, you will be tested 3 to 4 more times, at 1, 3, 6 and 12 months following your final dose of a COVID-19 vaccine.</p> <p>The number and timing of subsequent testing will depend on the date of your first data collection and the date of vaccination. For example, if you had received your final dose of a COVID-19 vaccine before the start of data collection (e.g., you received the final dose in January 2021 and you joined the study in March 2021), we will be unable to measure your immune response at 1-month post-vaccination. In this case, we may collect your first sample at 3-month post-vaccination, and you will only receive two additional tests (at 6- and 12-months post-vaccination).</p> <p>To help the research team track your immunization record, you may choose to use CANImmunize, a free digital tool for Canadians that securely stores your vaccination records and helps you get vaccinated on time. If you are uncomfortable with using this mobile application (app), one of the study's Research Coordinators will contact you regarding the date of your vaccination and the type of COVID-19 vaccine that you had received.</p>



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What will the test tell me?

Following each data collection, you will be able to find out the results of your antibody test from a secure, web-based portal created by the Ottawa Hospital using your unique study identifier (ID). The results will show you whether we had detected antibodies against antigens found in COVID-19 in your blood sample, as well as the level of antibody response.

Since COVID-19 antibody testing detects the presence of antibodies made in response to a COVID-19 infection, a positive result may tell you about an infection that happened in the past but will not tell you if you are currently infected. Antibodies are also produced when you have been vaccinated. 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. Currently, we do not know whether the presence of antibodies means you are protected against a reinfection. The level of immunity and how long immunity lasts are also not yet known.

What are the risks in providing a blood sample?

You may feel mild “pinprick” pain from the lancet (needle) and/or have a small bruise on your finger. A retractable safety lancet is used to eliminate the risk of accidental injury from the needle. There is also a risk of poking a nerve end, which is associated with increased pain and skin sensitivity at the puncture site. Therefore, it is important to carefully review the instructions before taking the blood sample and contact the research team if you have any questions or concerns beforehand.

There are no medical risks associated with this study. However, in case of injury directly resulting from participation in this research study, the cost of any treatment required not covered by the provincial health insurance plan will be covered by Bruyère Continuing Care.

What are the benefits to participating in this study?

Your participation in this study is entirely voluntary and you will not be paid for taking part in this research. Your participation, however, will provide scientists and public health officials important information about the COVID-19 pandemic. This information will help government officials, policymakers and researchers gain important insight and shape the direction of the country’s response to COVID-19 and help keep us safe.

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. The cost of shipping the samples will be covered by the research team.



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How long will you keep my data for?

Your de-identified blood samples will be securely stored in a biobank for future testing related to infectious diseases diagnostics. For example, your samples may be used to assess whether antibodies generated against COVID-19 will be protective against future novel coronaviruses. Samples will be stored for a maximum of 25 years after the study has been completed, at which point any unused samples will be destroyed.

How will you protect my identity and data?

All participants will have a unique study ID that will allow the researchers to link your responses to the questionnaire to your antibody test results. Only the lead investigators will have access to this information. Your personal information will not be attached to the blood samples that you provide and will be separated from your survey responses. The unused samples will be stored in a biobank at the Elisabeth Bruyère Hospital, which is only accessible to authorized research personnel and has security 24 hours a day.

The investigators will treat your personal information as confidential, although absolute privacy cannot be guaranteed. Research records identifying you may be inspected by lead investigators, Dr. Amy Hsu and Dr. Marc-Andre Langlois, and by the Bruyère Continuing Care Research Ethics Board for the purpose of monitoring the research.

The research team is also asking for your permission to collect your health card number so we can link your antibody testing results to healthcare data collected by the province. This will help us better understand how a person's immunity may be associated with the severity of COVID-19 that they experience, why some people have asymptomatic presentations, and their healthcare use from either an infection or from vaccination.

All personal information, like your health card number and name, will be securely stored on the Bruyère Research Institute's server. Once all of your data has been collected, linkage of your information and results to provincial healthcare databases will be performed by the Institute for Clinical Evaluative Sciences (ICES) – a not-for-profit research institute encompassing a community of research, data and clinical experts, and a secure and accessible array of Ontario's health-related data. The research team will use a secure and encrypted approach to transfer your data to ICES.



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Can participants change their mind about continuing in this study?

Your participation is voluntary and you may choose not to take part. Whatever you choose, it will not affect the usual medical care that you receive outside the study or your employment.

You can choose to end your participation in this research (called 'withdrawal') at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team within one month following data and sample collection.

Who can I contact for more information?

If you have questions about taking part in this study, you can reach the research team at C19ImmunityStudy@Bruyere.org.

This project has been reviewed and approved by the Bruyère Research Ethics Board (Protocol #M16-20-071). If you have any ethical concerns about the study or the way it is conducted, please contact the Bruyère Research Ethics Board at (613) 562-6262 Ext. 4003 or REB@bruyere.org. During the time of COVID it is usually not possible to reach REB staff by telephone. Accordingly, until more normal times, please contact the REB by email REB@bruyere.org.



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