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INFORMATION AND CONSENT FORM
(Non-hospitalized BQC19 Participant)

Title of the research project:	The Canadian COVID-19 Prospective Cohort Study
Protocol Number:	MP-37-2021-7524
Investigator responsible for the research project:	Suzanne N Morin MD MSc Research Institute of the McGill University Health Centre
Co-investigator(s)/sites:	Vicky Tagalakis MD MSc Jewish General Hospital François Lamontagne MD MSc Centre hospitalier universitaire de Sherbrooke Alain Piché MD MSc Centre hospitalier universitaire de Sherbrooke
Sponsor:	University Health Network (Toronto)
Funding:	University of Toronto, Toronto COVID-19 Action Initiative Fund, Canadian Institute of Health Research COVID-19 Rapid Research Fund, COVID-19 Immunity Task Force and the Canadian Frailty Network.

LEGAL REPRESENTATIVE
If you are a Legal Representative, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. If the participant gains the capacity to consent for him/herself, your consent for them will end. Throughout this form, "you" means the person you are representing.

INTRODUCTION
You are being invited to participate in a research study. You are invited to participate in this study because you have tested positive for the novel COVID-19 virus and have been asked to stay at home and self-isolate.

This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

WHY IS THIS STUDY BEING DONE?
There is currently very little information on why some people have a mild response to COVID-19 (do not require hospitalization), and why some people have a more severe response, requiring a stay in the hospital or even the intensive care unit (ICU).

The purpose of this study is to understand how people like you are affected by COVID-19. Our study aims to:

1. Examining differences and similarities between people with mild, moderate and severe symptoms of COVID-19 that might influence these outcomes (e.g., age, housing, postal code, medical condition, physical conditions etc.)
2. Investigate whether genetic variables (differences in the DNA sequence in each of our genomes that makes us all unique) may influence how people recover, or why some people get sicker than others. This information may be used to help develop vaccines and other therapeutic options.
3. Explore how cells in blood change, how they function over time (gene regulation studies), how the immune system responds, (serological and immunological testing) and how the coagulation system (blood clotting) is affected.
4. Put all these pieces together to identify the best way to treat patients in the future to ensure the best outcomes possible, and to develop tests (called biomarkers) that will help with targeting treatment to different groups of patients affected by COVID-19.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
It is anticipated that about 2000 COVID-19 patients will take part in this study, from research sites across Canada with about half coming from research sites located in Quebec. This study should take about 2 years to complete and the results should be known in about 6 months after the study is complete.

WHAT WILL HAPPEN DURING THIS STUDY?
If you agree to participate, the research team will follow you for one year following your COVID-19 diagnosis.

One week after your COVID-19 diagnosis you will be invited to participate in your first study visit either by videoconference or on the telephone. You will also be asked to attend follow-up visits **1-, 3-, 6- and 12-months after you received your diagnosis.** The follow-up visits may be held either in person (public health and infection control precautions permitting) or remotely by videoconference or on the telephone. In-person visits at (insert institution) will be held at (insert location). At each visit:

- We will ask you to answer some health-related questions
- You will also be given questionnaires to complete
- We will assess your current level of functional independence

Medical Information
You will be asked health-related questions about any lasting physical symptoms, mental health or mood concerns, your current level of function, any limitations, changes in your health, new medications, healthcare utilization and about your current occupation/work situation.

All data collected by the research team will be securely stored in an electronic database which will be maintained by the research team. The database can only be accessed by people who are involved in this research project. Please talk to the research team if there is information that you do not feel comfortable sharing.

The research team will use machine learning and artificial intelligence to analyze all the data to see if we can improve our understanding of COVID19 and improve care for our patients. Researchers who study artificial intelligence (computer learning) at the University of Toronto will use de-identified study data (will not contain any information that can be linked to you) so it will not be possible to identify you.

Questionnaires
You will be provided with questionnaires to complete at each visit. The purpose of these questionnaires is to find out what impact you feel your COVID-19 diagnosis has had on your health and quality of life. These questionnaires will take about 30-40 minutes to complete at each visit. They can be completed in person, by phone with a study coordinator, or a secure link can be emailed to you so that you can complete them yourself online.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

Functional Tests
If you feel you are well enough at your first study visit, we will test your functional independence by measuring your muscle strength, as well as your ability to walk and to do everyday tasks. Your arm and leg muscle strength will be tested against manual resistance. As part of the walking test, you may be asked to wear a small oxygen and heart rate sensor. We will also repeat these tests at all future follow up visits that are done in person.

Biobanque québécoise de la COVID-19 (BQC19)
As a participant in BQC19 you have given consent for the blood samples and data you provided to be available to Canadian and international researchers to conduct biomedical, including genetic, research on COVID-19 and other related diseases.

In order to help answer our study's objectives, the data collected by the CANCOV research team will be linked to information about you that was collected by BQC19. This may include information from your medical chart, results from tests run on the blood collected by BQC19 (including genetic tests) and answers to questionnaires. The information from the two studies will be linked at the level of the study databases so no information that can directly identify you such as your name, health card

number, etc. will be used.
This means that your participation in CANCOV will not require any blood draws and as much as possible we will avoid asking you questions that you have already answered as part of your participation in BQC19.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?
Your participation in this study will last for about 12 months.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?
There are some risks and discomforts associated with participation in this study.

The walking test may be tiring for you. Prior to initiating the test, you will be assessed for your ability to do this safely. The questionnaires are not associated with any risks but you may find them time-consuming.

The muscle strength test may cause you to feel muscle fatigue lasting a few hours or muscle soreness lasting 1-2 days following the test. About 1 in 5 people experience this. This will resolve on its own within a few hours or a couple of days.

When you donate your blood or tissue for genetic testing for research, you are sharing genetic information, not only about yourself, but potentially also about biological (blood) relatives who share your genes or DNA. The probability of identifying such heritable genetic changes is unlikely but should be considered. There is a risk that information gained from genetic research could eventually be linked to you. In Canada, there is a federal law that protects your genetic information. Third parties (like insurance companies) cannot require that you disclose the results of a genetic test. Every effort will be made to protect your privacy and the confidentiality of genetic testing results. However, there is a risk that someone could get access to your genetic information and identify you. The researchers believe the risk this will happen is small.

Due to the rapid pace of technological advances, the potential future use of genetic information is unknown and therefore the potential future risks also are unknown

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?
You may not receive direct benefit from participating in this study. We hope the information learned from this study will help other people with COVID-19 in the future.

VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW
Your participation in this study is voluntary. Therefore, you may refuse to participate. You may also withdraw from the ongoing project at any time, without giving any reason, by informing a member of the study team. Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled. You will be informed in a timely manner if any information becomes available that may impact your willingness to continue participating in this study.

The doctor responsible for this research project or the Research Ethics Board may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

If you withdraw or are withdrawn from the study, you may also request that the data already collected about you be removed from the study. If you request that your data be removed and the information already collected about you can be identified as yours it will be destroyed. If the data has been anonymized or was always anonymous (i.e. does not contain any information that can be used to

identify you), the data will continue to be used in the analysis of the study.

CONFIDENTIALITY
If you decide to participate in this study, the research team will only collect the information necessary to meet the scientific aims of this project.

All the information collected about you (study data) will be kept strictly confidential within the limits of the law. A code number will identify you. The code key linking your name to your study data will be kept in a secure location by the doctor in charge. When data collected by CANCOV is linked to the blood samples and data collected by BQC19 no information that can directly identify you such as your name, address or phone number etc. will be revealed.

Your study data will be stored in an electronic database which may be shared with national and international research partners and may be entered into other national and international databases. The sharing of this information is to allow national research teams working to stop the spread of COVID-19, to work together and increase worldwide research efforts. The information provided to them will not include information that can directly identify you. The CANCOV database will be securely stored, and will be maintained by the research team.

Records identifying you at (insert institution) will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may consult records that may identify you at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines. These individuals and organizations must adhere to strict privacy and confidentiality policies:

- Regulatory organizations, in Canada or abroad, such as Health Canada,
- University Health Network (study sponsor)
- The McGill University Health Centre (MUHC) Research Ethics Board (REB) which oversees the ethical conduct of this study in Quebec
- The (insert institution) and affiliated sites, to oversee the conduct of research at this location

Your study data may also be sent to the organizations listed above. Representatives of the MUHC REB, may see study data that are sent to the research ethics board for this study. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your study *code, sex, and month and year of birth*.
The following organizations may also receive study data:

- The Centre for Applied Genomics, Hospital for Sick Children, Toronto, Ontario who will be running the genetic analysis for the CGen HostSeq Databank on blood samples from this study.
- Other investigators in the CANCOV team, who will be analyzing the blood samples, collected for gene regulation, coagulation, biomarker and immune function analyses.
- University of Toronto research teams who will be using machine learning and artificial intelligence to analyze all the data to see if we can improve our understanding of COVID-19 and improve care for our patients.
- The COVID-19 Immunity Task Force (CITF) is a national initiative funded by the Government of Canada to perform research related to COVID-19 immunization. The CITF will collect data to share with researchers in Canada and internationally so as to understand the science underlying COVID-19 immunity, COVID-19 infection rates in the Canadian population, and to study related health outcomes.

The CANCOV research team is part of a Canadian wide government funded national initiative looking to understand the short- and long-term consequences of COVID-19, and the factors that predict those outcomes. Information about you kept in the CANCOV database may be shared with national and international research partners and may be entered into other national and international databases. This information may be used by academic researchers and their commercial partners in Canada and around the world. It is possible that shared study data may be stored on centralized servers including outside the province of collection, and on cloud servers. Access to CANCOV data will be controlled by the CANCOV research investigators and the CANCOV Data Access and Publications (DAP) committee, with appropriate ethics approval. The information provided to them will not include information that can directly identify you, such as your name, address or phone number. This de-identified data will be stored for 20 years.

In order to ensure open communication with you and your research team, we will ask for your consent to contact you by email. This will allow us to send you questionnaires for the study. Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

Any information and/or samples, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data and/or samples, that are transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number (RAMQ) or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

You can consult your research file to verify the information collected, and have it rectified if necessary.

INCIDENTAL FINDINGS

Incidental findings are abnormal findings that are discovered in the course of conducting research. Results of any research conducted using your samples or any incidental findings will not be shared with you or your physician, as the research conducted on your samples will have no diagnostic or therapeutic significance to you. Nor will these reports be placed in your medical file.

RETURN OF RESULTS

You will have the option to select your preference regarding whether you are willing to be contacted to learn about study findings. If you are willing to be contacted, the research team will provide you with a summary of the overall aggregate research results (results will not contain any identifiers) at the end of the study.

FUNDING OF THE RESEARCH PROJECT

This study is being sponsored by the University Health Network (Toronto) through funding obtained from University of Toronto, Toronto COVID-19 Action Initiative Fund, Canadian Institute of Health Research COVID-19 Rapid Research Fund, COVID-19 Immunity Task Force and the Canadian Frailty Network.

CONFLICT OF INTERESTS
The researchers have no conflict of interest to declare. The Principal Investigator at (insert institution) will receive financial compensation from the University Health Network for the work required in doing this clinical research. The site principal investigator and study team are not receiving any direct benefit from conducting the study.

COMPENSATION
If you decide to participate in this study, you will receive up to $XX compensation to cover travel expenses/parking fees for each study visit that you attend in person.

SHARING STUDY RESULTS
Results from this study will be presented at conferences and published in journals.

SHOULD YOU SUFFER ANY HARM
Should you suffer harm of any kind following any procedure related to the research study, you will receive the appropriate care and services required by your state of health. By agreeing to participate in this research project, you are not waiving any of your legal rights nor discharging the researcher, the sponsor or the institution, of their civil and professional responsibilities.

CONTACT INFORMATION
If you have questions or if you have a problem you think may be related to your participation in this research study, or if you would like to withdraw, you may communicate with the researcher or with someone on the research team at the following number: (insert number).

For any question concerning your rights as a research participant taking part in this study or if you have comments, or wish to file a complaint, you may communicate with:

> The Patient Ombudsman of the (insert institution) at the following phone number: (insert number).

OVERVIEW OF ETHICAL ASPECTS OF THE RESEARCH
The McGill University Health Centre Research Ethics Board reviewed this study and is responsible for monitoring it at all participating institutions in the health and social services network in Quebec.

Research Study Title: The Canadian COVID-19 Prospective Cohort Study

SIGNATURES

A. Signature of the participant

I have reviewed the information and consent form. Both the research study and the information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above.

I authorize the study team to link my data with biological samples and data collected by BQC19.

1) I authorize the research team to communicate with me by e-mail about this study. Yes ☐ No ☐

   E-mail address: _____

2) I am willing to be contacted to learn about study findings. Yes ☐ No ☐

3) I authorize a member of the research study to contact me in the future to ask if I am interested in participating in other research related to COVID-19. Yes ☐ No ☐

Name of participant	Signature	Date

Name of the legal representative (if applicable)	Signature	Date

Signature of the person obtaining consent

I have explained the research study and the terms of this information and consent form to the research participant, and I answered all his/her questions.

Name of the person obtaining consent	Signature	Date

B. Signature of the legal representative of the participant incapable of consenting

In my capacity as legal representative (curator, tutor, mandatary, or, if sudden incapacitation occurs, as spouse, close relative, or interested person), I have read the informed consent form. I acknowledge that this research and this informed consent form have been explained to me, that my questions have been answered and that I have been given sufficient time to make a decision.

I further acknowledge that I have been informed that in the event that the person I represent is again able to consent on his or her own and that his participation in the research is still ongoing, he or she will be asked to sign the informed consent form.

After consideration, I agree that the person I represent can participate in CANCOV under the conditions set out above. A signed and dated copy of this form will be forwarded to me.

Name of participant

Name of the legal representative (if applicable) Signature Date

As legal representative, please specify relation to participant:

❑ Curator
❑ Mandatary
❑ Tutor
❑ Spouse
❑ Close relative
❑ Interested person

Signature of the person obtaining consent

I have explained the research study and the terms of this information and consent form to the research participant, and I answered all his/her questions.

Name of the person obtaining consent Signature Date

C. Signature of the participant who regains capacity to consent

Today, I reviewed the information and consent form that my legal representative signed on my behalf when I enrolled in this research project and a copy of that signed consent was given to me.

I agree to continue my participation in this research project.

I understand that my participation is free and voluntary and that I can stop participating in this research project at any time I choose.

If I withdraw, any remaining data that has not already been analyzed will be destroyed.

Name of participant	Signature	Date

Signature of the person obtaining consent

I have explained the research study and the terms of this information and consent form to the research participant, and I answered all his/her questions.

Name of the person obtaining consent	Signature	Date