The Ottawa Hospital | L'Hôpital d'Ottawa

Minimal Risk Informed Consent Form for Participation in a Research Study

Study Title:	**Canadian COVID-19 Cohort Study (CCS): Study of the epidemiology of COVID-19 in Canadian healthcare workers**
OHSN-REB Number:	20210024-01H
Study Doctor:	Dr. Curtis Cooper The Ottawa Hospital Research Institute- General Campus Division of Infectious Diseases (613) 737-8899 x 78924
Sponsor/Funder(s):	COVID-19 Immunity Task Force

Non-emergency contact numbers are noted at the end of this document under the section heading "Whom do participants contact for questions".

INTRODUCTION

You are being invited to participate in a research study. You are being invited to participate in this study because you work in an acute care, rehabilitation, or complex care hospital. 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. The decision will not affect your employment.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine how many people develop COVID-19 infection and the risk factors for infection, to describe the changes in the carriage of antibodies against SARS-CoV-2 over time, the incidence of re-infection, the uptake of COVID-19 vaccines, and the psychological impact of working during the COVID-19 pandemic.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that 200 people will take part in this study in Ottawa. It is expected that over 2400 people will take part in this study from sites in Canada.

The length of the study will be 12 months, or until the end of the COVID-19 pandemic, whichever is shorter.

WHAT WILL HAPPEN DURING THIS STUDY?

1) An online survey at enrolment to assess your current risk factors (about 15 minutes)
2) Short online surveys every week about whether you have had any symptoms (about 2 minutes) *One out of five weeks, the survey will be longer to gather information about your exposure to ill people (about 5 minutes)
3) Every time you are tested for COVID-19, please complete the study online illness reports to inform the study of your test results, symptoms, and contact with ill people (about 5 minutes). This report should also be completed one every day you continue to have symptoms (about 2 minutes per day); and
4) Self-collect blood samples i) when you join, 6 months post baseline, and at the end of the study; ii) every 30 days after you test positive (by NP swab) for COVID-19 (for up to one year), and iii) within 3 days before receiving a COVID-19 vaccine and again 30 days after your final dose

Self- collection is similar to how people with diabetes check their blood sugar: a finger prick and a collection card on which you place 5 blood drops.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation in this study will last until the study ends (maximum length at this time is 12 months) or until the end of the COVID-19 pandemic, whichever is shorter.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

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.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study. Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected after you withdraw your permission.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation in the study may be stopped early, and without your consent, for reasons such as:

- The research team decides to stop the study
- The Ottawa Health Science Network Research Ethics Board withdraws permission for this study to continue
- The Sinai Health System Research Ethics Board withdraws permission for this study to continue

If you are removed from this study, the research team will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are no medical risks to you from participating in this study, but taking part in this study may make you feel uncomfortable. You may feel anxiety, panic, distress or other strong emotions when completing the study questionnaires. You do not have to answer any questions you do not want to.

You may have some acute pain and minor bruising at the site of blood collection; it is occasionally necessary to prick a second finger.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There is no direct benefit to being in the study beyond having access to test results. However, information learned from this study may help us reduce the risk of spreading COVID-19.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study.

Your data will be kept confidential. You will not be named in any reports. Your name, address, and phone number can only be accessed by the study staff and are needed to ship supplies to you. The information collected for the study will be kept on secure servers using encryption software for up to 120 days after the end of the study. It will then be transferred to the Sinai Health System server and kept there for 10 years before being destroyed. The following people may look at your personal health information to check that the information collected is correct and follows proper laws and guidelines:

- Representatives of the Sinai Health System Research Ethics Board
- The Ottawa Health Science Network Research Ethics Board, who oversees the ethical conduct of this study
- Ottawa Hospital Research Institute, to oversee the conduct of research at this location

No personal information will be shared outside the study except as required by law.

The COVID-19 Immunity Task Force (sponsor of the study) is funded by the Government of Canada to research COVID-19. Some of the data collected (COVID-19 infection status, underlying health conditions, social distancing practices, age, sex, ethnicity, education, living conditions, and travel experiences) will be shared with researchers in Canada and internationally to better understand immunity, infection rates, and health outcomes relating to COVID-19. This data will be stored in a database at McGill University indefinitely. All identifying information will be stripped from the data and replaced with a study code prior to sharing your data with them. General information about the research performed with these data will be available on the COVID-19 Immunity Task Force website, see https://www.covid19immunitytaskforce.ca

This research study is collecting information on race and ethnicity as well as other characteristics of individuals. This information provides the research team with some context when analyzing your samples and survey data. Providing information on your race or ethnic origin is voluntary.

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 shared in publications and presentations with researchers in Canada and internationally.

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared.

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

WHAT IS THE COST TO PARTICIPANTS?

There is no cost to taking part in the study. All supplies are provided by the study. The study pays to have supplies shipped to your home and returned to the lab.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study. If you decide to participate in this study, when you complete your baseline questionnaire and the first five weekly reports, you will receive an email asking you to choose the retailer for a $20 electronic gift card.

Additional draws will be made every 5 weeks throughout the study for a $10 electronic gift card. All weekly reports completed within the previous 5 week period will be eligible for each draw.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. You may contact the Principle Investigator, Dr. Coleman, at 647-267-2413 (weekdays between 8AM and 6PM Eastern time) or email covid.study@sinaihealth.ca. The results of the antibody tests will be shared with you within 6 months of the collection.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the investigators, COVID-19 Immunity Task Force, or involved institutions, nor does this form relieve the study doctor, COVID-19 Immunity Task Force or their agents of their legal and professional responsibilities.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have any questions, concerns, or would like to speak to the study team for any reason, please call:

Dr. Brenda Coleman, PhD	647-267-2413
Principal Investigator Name	Telephone

You can call 647-267-2413 or 416-294-6383 (weekdays between 8AM and 6PM Eastern time) or email covid.study@sinaihealth.ca anytime.

Dr. Curtis Cooper, MD	613-737-8899 x78924
Principal Investigator Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

ELIGIBILITY

Before you consent, it is important that we make sure that you are eligible to participate. Please check the items that apply to you:

- ☐ I am 18-75 years old
- ☐ I work in Ottawa
- ☐ I work, on average, 20 hours per week for a hospital– OR – I am a physician, nurse practitioner, or midwife who works, on average, 8 hours per week caring for patients
- ☐ I plan to be working for at least the next 3 months
- ☐ I do not meet one or more of these eligibility requirements

CONSENT

- ☐ I have read this information sheet and I understand the study procedures
- ☐ All my questions have been answered
- ☐ I do not give up any of my legal rights by signing this consent form
- ☐ I agree to be a part of the study

By typing my name, I confirm that the above statements are correct: _____

_____

OPTIONAL CONSENT

In addition to the basic study, I agree to study staff from Sinai Health System or Ottawa Research Institute contacting me by email or phone if there are other studies of

- ☐ COVID-19 and/or
- ☐ other infectious diseases

for which I might be eligible. I understand that I can decide at that time whether or not I wish to consider them and that I can ask to be removed from the list at any time. Whether or not I agree to participate in other studies will not affect my participation in this study or any other aspect of my employment.