

Letter of Information and Consent to Participate in a Research Study
Household members 18 years or older

Study Title: COVID-19 Cohort Study (CCS): Study of the epidemiology of COVID-19 in healthcare workers and their households

STUDY TEAM

Study investigator: Dr. Matthew Muller, Infection Prevention and Control, St. Michael's Hospital (416) 864-5568

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The principal investigator, co-investigators, and research staff do not have any conflicts of interest, financial or otherwise, related to this study or its outcome.

You are being asked to consider participating in this research study because you live with someone who works in a Canadian healthcare setting.

All research is voluntary – you do not have to participate and you can withdraw at any time.

Before agreeing to take part in this study, it is important that you read the information in this research consent form. It includes details we think you need to know to decide if you wish to take part in this study. If you have any questions, ask a study team member.

If you choose to participate in this study, you will need to sign this Letter of Information and Consent form. You should not sign this form until you are sure you understand the information. You may also wish to discuss the study with others such as your family doctor, a family member, and/or a close friend.

What is the purpose of the study?

This observational research study is to better understand how many people develop COVID-19 infection, how often infection is spread in households, and whether there are microbes or early immune responses (in our nose) that protect or make people more susceptible to infection. We are also studying the effectiveness of COVID-19 vaccines, how antibody levels (in your blood) change over time, and the psychological impact of working during the pandemic.

Who is being asked to participate?

People living with someone in the study who works in an acute care, rehabilitation, or acute care hospital and who sleep in the same dwelling (3 nights per week or more often, on average).

This study is being conducted across Canada and will enroll 2460 healthcare workers and their household members including about 250 healthcare workers from St. Michael's campus.

What do I need to do if I decide to participate?

1. An online survey at enrolment and every 12 months (~5-15 minutes)
2. Short online surveys
 - a. every 2nd week (~2 minutes); 1 week in 10 will be a bit longer (~5-7 minutes)
 - b. once about whether you intend to be vaccinated against COVID-19 (~3 minutes)
 - c. once about whether you intend to be re-vaccinated against COVID-19 (~3 minutes)
 - d. after each COVID-19 vaccination (~1 minute each dose)
3. Online illness/test questionnaires
 - a. When you are tested for COVID-19, even if you have no symptoms (~3-5 minutes);
 - b. When you have symptoms that might be COVID, even if you are not tested, (~3-5 minutes);
4. When someone else in your home develops an acute respiratory illness: collect nasal swabs and pledgets (small absorbent papers you put in your nose) on Days 1, 3, 5, 7, & 10 to test for immune responses (what is different in the noses of people who get COVID-19 and those who do not). *This is asked of ALL households where a person has COVID-19 and about 1 in 3 households where a person submits a swab when they have symptoms but test negative for COVID-19*
5. If you agree (optional), self-collect blood samples:
 - a. when you join,
 - b. 30 days after each positive test result for COVID-19,
 - c. 30 and 180 days after each dose of COVID-19 vaccine,
 - d. if you are not vaccinated: every 6 months after joining
 - e. If you are not re-vaccinated: every 6 months after your last dose of vaccine

Collection of the blood is similar to how people with diabetes check their blood sugar (with a finger pick and a card to put blood drops on).
The results will be shared with you after they are tested.

Participants will be asked to provide optional blood samples to attempt to find out whether they have been exposed to COVID-19. We will do this through a blood test, called serology, which looks for antibodies to the virus. Antibodies are substances that the body makes to protect people from infections like COVID-19. Please note, having antibodies does not necessarily mean you have developed immunity to COVID-19; it simply means you likely have been exposed to the virus at some point.

The results of the antibody testing will be shared with all participants. However, this will take several months since the labs are very busy at this time.

How long will the study last?

The study will last until the end of this new virus spread in Ontario or the end of the study. This means that the study will be at least 4 months and may last until December 1, 2023. You may withdraw at any time by emailing COVID.study@sinaihealth.ca or calling 416-294-6383.

Are there any benefits or risks to participating in the study?

- There are no physical risks to participating in the study.
- Collecting a nasal swab or pledget may be uncomfortable.
- If you choose to self-collect blood samples, you may have a small amount of pain or bruising at the prick site. It is occasionally necessary to prick a second finger.

- 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 spread of COVID-19.

Expenses associated with participating in the study

- 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.
- When you complete your baseline questionnaire and the first five bi-weekly reports, you will receive an email asking you to choose the retailer for a \$20 electronic gift card
- A draw will be made every 10 weeks throughout the study for a \$10 electronic gift card. All adult bi-weekly reports completed for each 10-week period will be eligible for the draw

Voluntary participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your employment or care. You may refuse to answer any question you do not want to answer. If you decide to withdraw from the study, information and specimens already gathered will not be destroyed.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Rights as a Participant

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Confidentiality

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 and call with test results. The information collected for the study will be kept on secure servers located in Canada using encryption software for up to 120 days after the end of the study (see <https://simplesurvey.com/canadian-hosted-survey-software>). It will then be transferred to the Mount Sinai Hospital 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: Representatives of the Unity Health Toronto Research Ethics Board.

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

Who can I talk to if I have questions?

You can email the study staff at COVID.study@sinaihealth.ca or call 416-294-6383 (weekdays between 9AM and 5PM) with any questions or comments.

The study protocol and consent form have been reviewed by the Unity Health Toronto Research Ethics Board. If you have any concerns about your rights as a research participant or your experiences while taking part in this

study, contact Dr David Mazer, chair of the Research Ethics Board at 416-864-6060 ext. 2557 during business hours.

ELIGIBILITY

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

- ☐ I am 18 years of age or older
- ☐ I sleep in the same home (3+ nights per week, on average) as someone who works at Unity Health, (St. Michael's campus)

CONSENT

- ☐ I have read this information sheet and I understand the study procedures
- ☐ I agree to be a part of the study

OPTIONAL SECTION

- ☐ I agree to collect blood samples as described above