Information sheet and consent form for 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 investigator: Dr. Matthew Muller, Infection Prevention and Control, St. Michael's Hospital (416) 864-5568
Funders: Weston Foundation, Physician Services Inc., & COVID-19 Immunity Task Force

You are being asked to take part in a research study. Please read the following explanation of what is being asked of you and about the study's risks and benefits before you decide if you would like to take part. Participation is voluntary.

What is the purpose of the study?

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. This study is for research purposes. It is being conducted across six Toronto-area hospitals and will enroll 800 healthcare workers and their household members.

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).

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

1. An online survey at enrolment to assess your current risk factors (~5-15 minutes)
2. Short online surveys every 5th week about whether you have had any respiratory symptoms and to ask about your exposure to ill people (~5-7 minutes)
3. Whenever you are tested for COVID-19 (even if you have no symptoms):
    a. complete an online illness report to inform the study of your test, the test results, your symptoms, and contact with ill people (~5 minutes);
    b. submit a swab to the study lab on the same day you submit one for COVID-19 testing (to assess how many viruses you may be carrying (viral load)); and
    c. complete online illness surveys every day you have symptoms (~2 minutes/day);
4. If someone 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 that tests negative for COVID-19.*
5. An online survey about whether you intend to be vaccinated against COVID-19 (~3 minutes)
6. An online questionnaire when (if) you are vaccinated against COVID-19 (~1 minute each time)
7. If you agree (optional), self-collect blood samples:
    a. when you join, in 6 months, at the end of the study.
    b. if you test positive for COVID-19, once, 30 days after your positive test;

c. if you test positive for COVID-19, every 30 days after your positive test; and.
d. if you are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

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).

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. This means that the study will be at least 4 months and may be as long as 12 months.

Are there any 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 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.
- A $20 electronic gift card is available for your participation. There is no other direct benefit to being in the study beyond having access to test results.

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. 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 8AM and 6PM) 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 or more per week, on average) as someone who works at Unity Health, (St. Michael's campus)
☐ I do not meet one or either of these criteria (requirements)

CONSENT

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

I agree to collect blood samples (*check all that you agree to*):

☐ when I join, in 6 months, and at the end of the study
☐ if I test positive for COVID-19, once, 30 days after my positive test
☐ if I test positive for COVID-19, every 30 days after my positive test
☐ if I am vaccinated against COVID-19, prior to receiving each dose and again 28 days after my final dose
Or ☐ none of the above