

**Letter of Information and Consent to Participate in a Research Study**  
**13-17 year old household members**

**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 blood antibody levels 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 complex 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?**

If you agree to join this study, you will be asked to do two things.

First, if someone in your home gets COVID-19 or a cold, we ask that you or your parents swab your nose and put a small piece of paper in your nose to collect germs and cells. We ask that you do this 4 or 5 times (about every second day).

Second, we ask that you self-collect blood samples (with your parent's help) to see if your body made special cells to attack COVID-19. You have several choices about this option. You can agree to be in the study and not collect any blood samples. You can decide to collect several samples (about twice per year) or you can agree to collect the blood samples now and change your mind later.

Collecting the blood is similar to how people with diabetes check their blood sugar levels: you prick your finger and put blood drops on a special card. The pin prick will cause pain for a short time and you may have some bruising. If you don't get enough blood the first time, some people need to prick a second finger.

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 last until December 1, 2023.

### **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 agree to collect blood samples, it can cause a small amount of pain or bruising where you prick your 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 \$10 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 (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](mailto: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 13 to 17 years of age
- ☐ 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)

### **CONSENT**

- ☐ I have read this information sheet
- ☐ I understand the study procedures
- ☐ I agree to be a part of the study
  
- ☐ I agree to collect blood samples when I join and then about every 6 months
- or -
- ☐ I do not want to collect blood samples