

**CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY**  
**(Adult household member)**

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

**Investigator/Study Doctor:** Dr. Allison McGeer, Microbiology & Infectious Diseases (416) 586-3123

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**Sponsor:** Weston Foundation, Physicians' Services Inc., Canadian Institutes of Health Research, & COVID-19 Immunity Task Force

**Introduction:**

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary (you can say yes or no).

**Background/Purpose:**

The purpose of this study is to better understand how many people develop COVID-19 infection, how often infection is spread in households, and whether there are microbes (cells and bacteria) or early immune responses (in our nose) that protect or make people more susceptible to infection. It is also studying the effectiveness of COVID-19 vaccines and how antibody levels change over time.

The information we learn from this study will be used to inform recommendations about the particular importance (or lack thereof) of protective measures for people working in hospitals as well as Canadian households.

**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 sleeps in the same home 3 nights per week or more often (on average).

**Study Visits and Procedures:**

1. An online survey at enrolment and every 12 months (~5-15 minutes)
2. Short online surveys
  - every 2<sup>nd</sup> week (~2 minutes); 1 week in 10 will be a bit longer (~5-7 minutes)
  - once about whether you intend you be vaccinated against COVID-19 (~3 minutes)
  - once about whether you intend to be re-vaccinated against COVID-19 (~3 minutes)
  - after each COVID-19 vaccination (~1 minute each dose)
3. Online illness/test questionnaires
  - when you are tested for COVID-19 (even if you have no symptoms) (~3-5 minutes);
  - 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 with symptoms submits a swab that tests negative for COVID-19.

5. If you agree (optional), self-collect blood samples:

- when you join;
- 30 days after each positive test result for COVID-19;
- 30 and 180 days after each dose of COVID-19 vaccine;
- if you are not vaccinated: every 6 months after joining;
- 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 the sample is tested. This takes several months.*

### **How long will the study last?**

The study will last until the end of this new virus spread in Ontario or the end of study funding. This means that the study will be at least 4 months and may last until December 1, 2023.

### **Risks and Benefits:**

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

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

### **Confidentiality:**

Your data will be kept confidential (not shared with others). Your name will not be in any reports. Your name, address, and phone number can only be seen by the study staff and are needed to ship supplies to you and to call you about study procedures, as needed. Your email address will be used by the electronic data capture application ([simplesurvey.com](https://www.simplesurvey.com)) to send you study emails and link to your questionnaires for the duration of the study. SimpleSurvey will not share your email or any information about you with anyone outside of this study.

The information collected for the study will be kept on secure servers using encryption software (so only the study staff can find and understand it) 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 (name, address) to check that the information we collected is correct: Representatives of the University Health Network Research Ethics Board or Health Canada.

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

### **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.

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

### **Withdrawal from the Study:**

You may withdraw from the study (stop participating) at any time.

### **Costs and Reimbursement:**

There is no cost to taking part in the study. All swabs and pledgets 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 when you complete your baseline questionnaire and the first five biweekly reports.

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

**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, sponsors or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**Conflict of Interest:**

The investigators declare no conflicts of interest.

**Questions about the Study:**

If you have any questions, concerns or would like to speak to the study team for any reason, please email the coordinator at [covid.study@sinaihealth.ca](mailto:covid.study@sinaihealth.ca) or call (416) 294-6383 between 9AM and 5PM.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be emailed a copy of this consent form.

**ONLINE ONLY:**

**The UHN research ethics board requires a verbal consent from all participants**

**Please call (416) 294-6383 between 9AM and 5PM to review this form with a research staff**

If others in your home agree to participate, we can consent them during the same call or at another time.

**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 (at least 3 nights per week, on average) as someone who works at University Health Network (Toronto General, Toronto Western, Princess Margaret, or Toronto Rehab)

**Consent:**

- ☐ This study has been explained to me and any questions I had have been answered.
- ☐ I know that I may leave the study at any time. I agree to the use of my information as described in this form.
- ☐ I agree to take part in this study.

**OPTIONAL SECTION**

- ☐ I agree to self-collect blood samples as described above

FOR INFORMATION ONLY