CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY (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

Contact Information: Brenda Coleman, PhD, Infectious Disease Research (647) 267-2413

Sponsor: Weston Foundation, Physicians' Services Inc., & 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, how antibody levels change over time, and the psychological impact of working during the pandemic.

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 2nd week (~2 minutes); 1 week in 10 will be a bit longer (~5-7 minutes)
3. Whenever you are tested for COVID-19 (even if you have no symptoms), complete an online illness/test report to inform the study of your test, the test results, your symptoms, and contact with ill people (~5 minutes);
4. When you have symptoms that might be COVID (even if you are not tested), complete an illness/test report (~5 minutes);
5. 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.*
6. An online survey about whether you intend to be vaccinated against COVID-19 (~3 minutes)
7. An online questionnaire when (if) you are vaccinated against COVID-19 (~1 minute each time)

8. If you agree (optional), self-collect blood samples: when you join and again every 6 months, 30 days after/if you test positive for COVID-19, and if you are vaccinated against COVID-19, prior to receiving your first dose and again 30 days after your 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). Results of the blood tests will be emailed to you several weeks after your first sample arrives at the study office, after your final dose of vaccine (if you are vaccinated), and after your final sample at the end of the study (which will include all results of all samples submitted).

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 September 30, 2023. You may withdraw at any time by emailing COVID.study@sinaihealth.ca or calling 416-294-6383.

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. 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.

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 or call (416) 294-6383 between 8AM and 6PM.

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 8AM and 6PM 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

Study Participant's Name	Date

My signature below means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person	Signature	Date Obtaining Consent

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness	Signature	Date

Relationship to Participant