Information Sheet and Consent Form
Adults Living with a Healthcare Worker

Title of Protocol: COVID-19 Cohort Study (CCS): Study of the epidemiology of COVID-19 in healthcare workers and their households
Study Investigator: Dr. Jeff Powis, Infection Prevention & Control (416) 469-6252
Funder: Weston Foundation, Physicians' Services Inc., Canadian Institutes of Health Research, & COVID-19 Immunity Task Force

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 and how blood antibody levels change over time. This study is for research purposes.

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)

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

1. An online survey at enrolment and every 12 months (~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 that tests negative for COVID-19.*
5. If you agree (optional): self-collect blood samples:
    a. when you join;
    b. 30 days after each positive test 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 by email after they are tested.

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

Are there any risks or benefits 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.
- 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 (1 certificate is drawn for every 500 biweekly reports in each period).
- There is no other 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.
- Taking part in the study is voluntary. You can leave the study at any time by contacting the study coordinator. You can 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.

Data Collection and Use

Although this research is being conducted by researchers from across Canada, all data you provide is being handled by research staff from Sinai Health. Examples of the types of data we collect includes your name, ethnic background, date of birth, health conditions, and results of tests that you may have had. We will only collect the information that we need do the research. We will get this information by asking you to complete online questionnaires. Your study data will be coded (with a number) so that it no longer contains your name, address or anything else that could identify you. Only the study staff will be able to link your coded study data to you.

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 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 7 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 Michael Garron Hospital Research Ethics Board. Please note that email is not considered a secure way to transmit confidential information.

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

When you give your consent, you keep all your legal rights relating to the research team members and the hospitals. The research team members and hospitals involved in this study have legal and professional duties to you and others taking part.

Who can I talk to if I have questions?

If you have any questions, concerns, or would like to speak to the study team for any reason, please call Dr. Powis at 416-469-6252 or Dr. Coleman, PhD, at COVID.study@sinaihealth.ca or call (416) 294-6383 (weekdays between 9am and 5pm).

This study has been reviewed by the Michael Garron Hospital (MGH) Research Ethics Board (REB). The REB is independent of the researchers. If you have any concerns or questions about your rights or your experiences as a research participant, you may contact Dr. Sherry Rezaie, Chair of the MGH REB at 416-469-6580 ext. 3853, 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 Michael Garron Hospital or an associated rehab/complex care hospital

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 self-collect blood samples as described above