Information Sheet and Consent Form
Adults Living with a Healthcare Worker

Study Title: COVID-19 Cohort Study (CCS): Study of the epidemiology of COVID-19 in healthcare workers and their households
Study Investigator: Dr. Samira Mubareka, Microbiology & Infectious Diseases, (416) 480-6100 ext 4823
Funders: Weston Foundation, Physicians' Services Inc., Canadian Institutes of Health Research, & COVID-19 Immunity Task Force

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You are being asked to consider participating in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood. This form explains the purpose of this research study, provides information about the study , the tests and procedures involved, possible risks and benefits, and the rights of participants.

Please ask the study staff or one of the investigator(s) to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study. If you wish, someone may be available to verbally translate this form into your preferred language.

Participating in this study is your choice (voluntary). You have the right to choose not to participate or to stop participating in this study at any time.

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 antibody levels (in your blood) change over time.

Who is being asked to participate?

People living with someone in the study who works in an acute care, rehab, or complex care hospital associated with Sunnybrook Health Sciences Centre and who sleep in the same dwelling 3 nights per week or more often, on average.

This study is being be conducted across 13 sites in Canada and will enroll 2460 healthcare workers and their household members including about 300 healthcare workers from Sunnybrook Health Science Center.

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

1. An online survey at enrolment and every 12 months (~5-15 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 test negative for COVID-19*
5. If you agree (optional), self-collect blood samples:
    a. when you join;
    b. 30 days after each positive test result 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, and/or
    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 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 the study. 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 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.
- If you experience any study-related injuries, you should contact Brenda Coleman, Sinai Health, at 416-294-6383.
- You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff.

Are there any benefits to participating in the study?

- 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.
- 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 your $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 that 10-week period will be eligible for the draws (1 certificate is drawn for every 500 biweekly reports in each period).

Are there any costs to participating in the study?

- 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.
- By agreeing to participate in this study, you do not give up any of your legal rights.

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 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 Sunnybrook Research Ethics Board or Health Canada. No personal information will be shared outside the study except as required by law.

Who can I talk to if I have questions?

You have the right to ask questions and to receive answers throughout this study.

If you have any questions, concerns, or would like to speak to the study team for any reason, please call Dr. McGeer at 416-586-3123 or Dr. Coleman, PhD, at covid.study@sinaihealth.ca or call 647-267-2413.

The Sunnybrook Research Ethics Board has reviewed this study. If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 88144.

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 per week, on average) as someone who works at Sunnybrook Health Sciences Centre or an associated rehab/complex care site

DOCUMENTATION OF INFORMED CONSENT

A copy of this informed consent form will be available on your personal study dashboard once it is signed and dated.

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

By signing this form, I confirm that:

- This research study has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research study
- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form
- I authorize access to my personal information and research study data as explained in this form
- I have agreed to participate in this research study

OPTIONAL SECTION

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