COVID-19 Cohort Study (CCS):
Study of the epidemiology of COVID-19 in healthcare workers and their households
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
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Co-Investigators:	Dr. Allison McGeer, MD, Senior Clinician Scientist Dr. Brenda Coleman, RN PhD, Infectious Disease Epidemiologist
Research Coordinator:	Dr. Brenda Coleman, RN PhD, 647-267-2413
Funders:	Weston Foundation, Physicians' Services Inc., & COVID-19 Immunity Task Force

Study information
You are being invited to take part in a research study. Please read the following explanation of what is being asked of you and about the study's risks and benefits before you decide if you would like to take part. Participation is voluntary.

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, how antibody levels change over time, and the psychological impact of working during the pandemic.

Who is being asked to participate?
People living with someone in the study who works in an acute care hospital and who sleep in the same dwelling (3 nights per week or more often, on average). We are planning to enrol 300 household members.

What do I need to do if I decide to participate?
1. An online survey at enrolment to assess your current risk factors (~5-15 minutes)
2. Short online surveys every 5th week about whether you have had any respiratory symptoms and to ask about your exposure to other ill people (~5-7 minutes)
3. When you are tested for COVID-19:
    a. Complete online illness reports to inform the study of your test results, symptoms, and contact with ill people (~5 minutes) and other reports each day you continue to have symptoms (~2 minutes/day)
4. When someone 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. An online survey about whether you intend to be vaccinated against COVID-19 (~3 minutes)

6. An online questionnaire when (if) you are vaccinated against COVID-19 (~1 minute each time)
7. If you agree (optional), self-collect blood samples:
    a. when you join, in 6 months, and at the end of the study;
    b. if you test positive for COVID-19, once, 30 days after your positive test;
    c. if you test positive for COVID-19, every 30 days after your positive test; and.
    d. if you are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

        Self-collection is similar to how people with diabetes check their blood sugar (with a finger prick and a collection card to put 5 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. This means that the study will be at least 4 months and may be as long as 12 months.

Are there any benefits or 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 volunteer to self-collect blood specimens, you may have some pain and 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.
- A $20 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. However, information learned from this study may help us reduce the risk of spreading 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.

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 care. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying “pass”.

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

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. 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 Mount Sinai Hospital Research Ethics Board or Health Canada.

No personal information will be shared outside the study except as required by law. By agreeing to participate in this study, you do not give up any of your legal rights.

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. Arnoldo at 905-494-2120 ext 57810 or study staff at covid.study@sinaihealth.ca or call (416) 294-6383 (weekdays between 8AM and 6PM).

If you have any questions about your rights as a research participant or have concerns about this study, call Drs. Paula Chidwick or Herbert Brill, Co-Chairs of the William Osler Health System Research Ethics Board (REB) at 905-494-2120 ext. 50448. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Documentation of Informed Consent

You will be given a signed copy of this consent form after it has been signed and dated by you.

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By signing this consent form I agree that:
This study has been explained to me and any questions I had have been answered.

- I know that my participation is voluntary and that I may leave the study at any time.
- 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 any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form

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 William Osler Health System
☐ I do not meet one or more of these requirements (statements)

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 (*check all that you agree to*):

☐ when I join, in 6 months, and at the end of the study
☐ if I test positive for COVID-19, once, 30 days after my positive test
☐ if I test positive for COVID-19, every 30 days after my positive test
☐ if I am vaccinated against COVID-19, prior to receiving each dose and again 28 days after my final dose
Or ☐ none of the above