

Information Sheet and Consent Form for Healthcare Workers

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

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?

We are planning to enrol 300 healthcare workers from William Osler Health System. We will be enrolling 2460 healthcare workers from hospitals across Canada. People working in an acute care, rehabilitation, or complex care hospital associated with William Osler Health System are eligible if they:

- are 18 to 75 years old
- work anywhere in the hospital for more than 20 hours per week
 - OR is an MD/NP with privileges who works at least 8 hours per week in the hospital
- are available for at least the next 3 months (not retiring or going on leave), and
- have convenient access to a computer or a cell phone with internet access (to complete surveys and receive information about the study)

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

- 1) An online survey at enrolment to assess your current risk factors (~15 minutes)
- 2) Short online surveys every week about whether you have had any symptoms (~2 minutes). One week in five, the survey will be longer and 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) An online survey about whether you intend to be vaccinated against COVID-19 (~3 minutes)
- 5) An online questionnaire when (if) you are vaccinated against COVID-19 (~1 minute each time)
- 6) An online survey at the end of the study to assess the psychological impact of working during the pandemic (~4 minutes)
- 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/or
 - 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). You can choose to have it collected one way and change your mind later by letting us know

The results will be shared with you after they are tested
- 8) If you agree (optional), ask others in your household to participate (as detailed below)

If you have others living in your home...

We ask that you involve them in the study to help us measure risk factors for transmission within households and whether there are microbes or early immune responses (in our nose) that protect or make people more susceptible to infection. Everyone who sleeps in the same dwelling as you 3 or more nights per week, on average, is being asked to participate.

If others in your home join the study, you are asked to...

- Do the first 6 things listed above AND
- Give us email addresses to contact the adults who give you permission to include them in the study so we can send them an invitation to participate
- Complete weekly symptom reports for everyone in your home (about 1 minute per person)
- Do a very short online survey about each child (about 2 minutes per child)
- Do a short online questionnaire when (if) each child is vaccinated against COVID-19 (~1 minute each time)
- When children are tested for COVID-19: complete illness reports (~ 5 minutes for the first and ~2 minutes for all reports)
- When someone in your home becomes ill, collect [or supervise the collection of] nasal swabs and pledgets (small absorbent papers put in the nose) for yourself and/or your children on Days 1, 3, 5, 7 & 10 to test for immune responses - to see if there are differences in the microbes in the noses of people who get COVID-19 and those who don't. *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.*
- Optional: if you and they agree, collect blood samples from children (using a finger prick and collection card)
 - when they join, in 6 months, and at the end of the study;
 - if they test positive for COVID-19, once, 30 days after their positive test;
 - if they test positive for COVID-19, every 30 days after their positive test; and/or
 - if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

Adults (18 years or older) are asked to do:

- 1) one baseline questionnaire (~5 to 15 minutes)
- 2) an online report every 5th week (~5-7 minutes)
- 3) when they are tested for COVID-19: do an online illness report- (~ 5 minutes for the first and ~2 minutes for all reports)
- 4) when someone else in the home becomes ill, collect swabs and pledgets (small absorbent papers) on Days 1, 3, 5, 7 & 10 to test for immune responses. *This is asked of ALL households where a person has COVID-19 and about 1 in 3 households where a person submits a swab that tests negative for COVID-19.*
- 5) An online survey about their intent to be vaccinated against COVID-19 (~3 minutes)
- 6) An online questionnaire when (if) they are vaccinated against COVID-19 (~1 minute each time)
- 7) If they agree (optional), self-collect blood samples:
 - a. at enrolment, in 6 months, and at the end of the study;
 - b. if they test positive for COVID-19, once, 30 days after their positive test;
 - c. if they test positive for COVID-19, every 30 days after their positive test; and/or
 - d. if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

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 for blood specimens to be taken, 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. A \$10 electronic gift card is available for children who participate. 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 employment status. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying “pass”.

If you choose to withdrawal your participation in this research study, any data collected from you will be retained from the study up until the point of withdrawal

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 Markham Stouffville 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. Arnaldo 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.

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

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 consent, it is important that we make sure that you are eligible to participate. Please check the items that apply to you:

- I am 18-75 years old
- I work for William Osler Health System or an associated rehabilitation or complex care site
- I work, on average, 20 hours per week for the hospital – OR – I am a physician or nurse practitioner who works, on average, 8 or more hours per week caring for ill patients
- I plan to be working for the hospital for at least the next 3 months (not planning to retire or go on leave)
- I do not meet one or more of these eligibility requirements

CONSENT

- I have read this information sheet and I understand the study procedures
- I agree to be a part of the study

OPTIONAL SECTION

OPTION #1: Blood

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 the final dose
- Or none of the above

OPTION #2: Invite people who live in my home to participate

- I agree to having others in my household participate in this study
 - adult(s) 18 years of age or older
 - child / children younger than 17 years old

If adult(s) checked:

By providing an email address for adults (18 years or older), they have agreed to the study sending them an email invitation to join the study (they can decide whether or not to join once they read it):

1) Nickname* for adult: _____ Email address: _____

*Nicknames are used to identify different people with the same email address and, if they agree to join the study, to identify them in weekly symptom reports.

If child/children checked:

1) Nickname* for child: _____ Age** : _____ years (enter 0 if <1 year)

- I understand the study procedures for children
- I am a parent or legal guardian of this child
- I agree to this child being a part of the study

OPTIONAL:

I agree to collect blood samples from this child (*check all that you agree to*):

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