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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Co-Investigators:	Dr. Allison McGeer, MD, Senior Clinician Scientist Dr. Brenda Coleman, PhD, Infectious Disease Epidemiologist
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Funders:	Weston Foundation, Physicians' Services Inc., & COVID-19 Immunity Task Force

Introduction

You are being invited to take part in a research study because you work in healthcare. 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 and every 12 months to assess possible sources of exposure (~15 minutes)
2) Short online surveys every second week about whether you have had any symptoms (~2 minutes). One week in ten, 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 (even if you have no symptoms), complete an online illness/test report to inform the study of your test results, symptoms, and contact with ill people (~5 minutes)When you have symptoms that might be COVID (even if you are not tested): complete an online illness/test report (~ 5 minutes)
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 dose)
6) An online questionnaire assessing your level of stress every 6 months (~2 minutes)
7) An online survey at the end of the study to assess the psychological impact of working during the pandemic (~4 minutes)
8) Self-collect blood samples:
    a. when you join and every 6 months after that;
    b. 30 days after/if you test positive for COVID-19; and
    c. If you are vaccinated against COVID-19, prior to receiving each dose and again 30 days after the each 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
9) 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 (any age) who sleeps in the same dwelling as you 3 or more nights per week, on average, can take part

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 biweekly 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)
- 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 and again every 6 months, before and again 30 days after each COVID-19 vaccination, and 30 days after they test positive for COVID-19

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 and may last until September 30, 2023.

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.

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.

Data sharing

The COVID-19 Immunity Task Force (sponsor of the study) is funded by the Government of Canada to research COVID-19. Some of the data collected (COVID-19 infection status, underlying health conditions, social distancing practices, age, sex, ethnicity, education, living conditions, and travel experiences) will be shared with researchers in Canada and internationally to better understand immunity, infection rates, and health outcomes relating to COVID-19. This data will be stored in a database at McGill University indefinitely. All identifying information will be stripped from the data and replaced with a study code prior to sharing your data with them. General information about the research performed with these data will be available on the COVID-19 Immunity Task Force website, see https://www.covid19immunitytaskforce.ca

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.

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 with privileges who works, on average, 8 or more hours per week caring for patients
☐ I plan to be working for/with the hospital for at least the next 3 months (not planning to retire or go on leave)
OR
☐ 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

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 their blood samples.

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
☐ prior to receiving each dose and again 30 days after each dose of COVID-19 vaccine
Or ☐ none of the above

*Nicknames are used to identify people with the same email address and, if you agree to them joining the study, to identify children for illness and biweekly reports and blood samples

**An email will be sent to you with a link to *assent* forms for each child 12 to 17 years of age. Please have them complete the form if they agree to participate.

OPTIONAL:

☐ In addition to the basic study, I agree to study staff from Sinai Health contacting me by email or phone if there are other studies of COVID-19 and/or other infectious diseases for which I might be eligible. I understand that I can decide at that time whether or not I wish to consider them and that I can ask to be removed from the list at any time. Whether or not I agree to participate in other studies will not affect my participation in this study or any aspect of my employment.

By typing my name, I confirm that the above statements are correct: _____

SUBMIT / DO NOT SUBMIT BUTTONS