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

Information Sheet and Consent Form for Healthcare Workers

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 COVID-19 pandemic. This study is for research purposes.

Who is being asked to participate?

People working in an acute care, rehabilitation, or complex care hospital who:

- are 18 to 75 years old
- work anywhere in the hospital for more than 20 hours per week
    - OR is a MD/NP with privileges who spends 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/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 (~2 minutes). One week in ten, the survey will be a bit 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)
4. When you have symptoms that might be COVID (even if you are not tested), complete an online illness/test report (~ 5 minutes);
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 dose)
7. An online questionnaire assessing your level of stress every 6 months (~2 minutes)
8. An online survey at the end of the study to assess the psychological impact of working during the pandemic (~4 minutes)
9. Provide blood samples:
    a. when you join and every 6 months after that;
    b. 30 days after/if you test positive for COVID-19
    c. if you are vaccinated against COVID-19, prior to receiving your first dose and again 30 days after the final dose

    You can decide whether to have it collected at the hospital or self-collect it. 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 by email after they are tested

10. 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 9 things listed above AND
- Give us an email address to contact the adults who give you permission to include them in the study so we can send them an invitation to participate
- Do a very short online survey about each child (about 2 minutes per child)
- Complete bi-weekly symptom reports for children (<18 years old) in your home (about 1 minute per person)
- 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 an illness/test report
- 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. *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, 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 or the end of study funding. This means that the study will be at least 4 months and may last until September 30, 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 is uncomfortable.
- If you choose to have blood collected at your hospital's blood collection lab, you may have some pain and bruising at the site. If blood is self-collected, it is occasionally necessary to prick a second finger. You may have a small amount of pain or bruising at the prick site.
- 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 and K-10 questionnaires and the first five bi-weekly reports, you will receive an email asking you to choose the retailer for your $20 electronic gift card
- If you enrol children, you will also receive an email asking you to choose (or have them choose) the retailer for their $10 gift card
- 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.

Study information

Study investigator: Dr. Jeff Powis, Infection Prevention & Control (416) 469-6252
Funders: Weston Foundation, Physicians' Services Inc., & COVID-19 Immunity Task Force

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.

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

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 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.

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. Powis at 416-469-6252 or Dr. Coleman, PhD, at COVID.study@sinaihealth.ca or call (416) 294-6383 (weekdays between 8AM and 6PM).

If you have any questions or concerns about your rights as a research participant or your experiences while taking part in this study, please contact Dr. Sherry Rezaie, Chair of the Michael Garron Hospital Research Ethics Board at 416-469-6580, ext. 3853.

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 at Michael Garron Hospital
- ☐ I work, on average, 20 hours per week for the hospital – OR – I am a physician or nurse practitioner who works, on average, 8 hours per week caring for ill patients
- ☐ I plan to be working for the hospital for the next 3 months (I am 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

How do you prefer to collect blood samples for yourself?

- ☐ I will have my blood collected at the lab at Michael Garron
- ☐ I will self-collect my blood (the study will mail the collection kits to you)

OPTIONAL SECTION

Other household member(s):

- ☐ 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 adults checked:

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

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 bi-weekly symptom reports, swabs, and blood samples. Please use a nickname that will not make it easy for *someone else* to identify who they are.

If child/children checked:

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 when they join and again every 6 months afterwards, and 30 days after [if] they test positive for COVID-19

*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 bi-weekly symptom reports, swabs, and blood samples. Please use a nickname that will not make it easy for *someone else* to identify who they are.

**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.