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

Information Sheet and Consent Form for Hospital Staff

Study information

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Funders: Weston Foundation, Physicians' Services Inc., Canadian Institutes of Health Research, & COVID-19 Immunity Task Force

You are being asked 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 COVID-19 pandemic.

Who is being asked to participate?

People working in an acute care, rehabilitation, or complex care hospital associated with Sinai Health System who:

- *are 18 to 75 years old*
- *work anywhere in the hospital for at least 20 hours per week*
    - *OR is a MD/NP with privileges who spends 8 hours or more per week in the hospital*
- *available for 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*
    - i. *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)*
    - **ii.** *once about whether you intend to be vaccinated against COVID-19 (~3 minutes)*
    - iii. *once about reasons to/not to be re-vaccinated against COVID-19 (~3 minutes)*
    - iv. *after each COVID-19 vaccination (~1 minute each dose)*
    - v. *every 6 months to assess your level of stress (~2 minutes)*
    - **vi.** *once at the end of the study to assess the psychological impact of working during the pandemic (~4 minutes)*
3. *Online illness/test questionnaires*
    - **i.** *When you are tested for COVID-19, even if you have no symptoms (~5 minutes)*
    - vii. *When you have symptoms that might be COVID, even if you are not tested (~ 5 minutes);*
4. *Provide blood samples:*
    - i. *when you join,*
    - ii. *30 days after each positive test result for COVID-19,*
    - viii. *30 and 180 days after each dose of COVID-19 vaccine,*
    - iii. *If you are not vaccinated: every 6 months after joining*
    - ix. *If you are not re-vaccinated: every 6 months after your last dose of vaccine. You can decide whether to have blood 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 after they are tested.*

5. 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…

5. *Do the first 4 things listed above AND*
6. *For adults (18 years or older): 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*
7. *For each child younger than 18 years old*
    i. *Do online surveys*
    ii. *at enrolment and again every 12 months (~2 minutes per child)*
    iii. *Every second week(~1 minute per child)*
    iv. *Illness/test questionnaires: When children are tested for COVID-19 (~2 minutes)*
    v. *after each COVID-19 vaccination (~1 minute each dose)*
    vi. *once about your reasons to/not to vaccinate each child (~3 minutes each)*
    vii. *once about your reasons to/not to re-vaccinate each child (~3 minutes each)*
    viii. *OPTIONAL: If you and they agree, collect blood samples (using finger prick and collection card) when they join and again 6 months after each dose of COVID-19 vaccine. If they are not vaccinated: every 6 months after enrolment. If they were vaccinated, but not re-vaccinated: every 6 months after their last dose of vaccine.*
8. *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*
9. *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 test negative 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 the study funding. 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 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 have blood collected at your hospital's phlebotomy 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.*
- *There is no 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.*

Expenses associated with participating in the study

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 a $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 a $10 gift card after completing the baseline and first 5 biweekly questionnaires for them
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).

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".

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.

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 about you (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. McGeer at 416-586-3123 or Dr. Coleman, PhD, at covid.study@sinaihealth.ca or call 647-267-2413 (weekdays between 8AM and 6PM).

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number at 416-586-4875. 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.

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 Sinai Health System (either Mount Sinai Hospital or Bridgepoint Active Healthcare)
☐ 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 at least the next 3 months (I am not planning to retire or go on leave)

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 phlebotomy lab at Mount Sinai
☐ I will self-collect my blood

OPTIONAL SECTIONS

OPTION #1: Other household member(s):

☐ I agree to having others in my household participate in this study (check all that apply):
- ☐ adult(s) 18 years of age or older
- ☐ child or children 17 years or younger

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):
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.*

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

**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.*
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.

OPTION #2

☐ 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.

OPTION #3

We are asking for permission to share with other researchers what is left over of your blood samples after our study tests are complete.

Because SARS-Cov-2 is a new virus, many researchers are working to understand this infection and the effectiveness of vaccines. Having enough different samples is important for these studies. These researchers may be at universities, hospitals, private companies, or in public health departments or laboratories, within or outside of Canada. It is possible that the research conducted using your samples and/or study data may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products. If this happens, there are no plans to provide payment to you.

A group of study doctors will make sure that requests for your samples make the best use of them and that they are only used in research related to COVID-19 or other respiratory infections. If parts of your leftover samples and data are shared, they will be de-identified; that is, it will not be possible for anyone outside this study to find out who you are or to link your sample or data to you. If information is transferred outside of Canada, it will be subject to the laws of the country where it is stored, which may not be as strict as Canadian laws.

These samples may be stored and used for up to 15 years.

☐ I agree to share the leftover blood samples with other researchers
☐ I do not agree to share the leftover samples