Information Sheet and Consent Form for Healthcare Workers

Title of Protocol: COVID-19 Cohort Study (CCS): Study of the epidemiology of COVID-19 in healthcare workers and their households
Principal Investigator: Dr. Jeff Powis, Infection Prevention & Control (416) 469-6252
Funders: Weston Foundation, Physicians' Services Inc., Canadian Institutes of Health Research, & COVID-19 Immunity Task Force

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:
    a. 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)
    b. once about whether you intend to be vaccinated against COVID-19 (~3 minutes)
    c. once about reason to be/not to be re-vaccinated against COVID-19 (~3 minutes)
    d. once when (if) you are vaccinated against COVID-19 (~1 minute each dose)
    e. every 6 months to assess your level of stress (~2 minutes)
    f. once at the end of the study to assess the psychological impact of working during the pandemic (~4 minutes)
3. Online illness/test questionnaires:
    a. when you are tested for COVID-19 (even if you have no symptoms) (~5 minutes);
    b. when you have symptoms that might be COVID (even if you are not tested): (~5 minutes);
4. Provide blood samples:
    a. when you join;

b. 30 days after each positive test result for COVID-19;
c. 30 and 180 days after each dose of COVID-19 vaccine;
d. if you are not vaccinated: every 6 months after joining; and/or
e. if you are not re-vaccinated: every 6 months after your last dose of vaccine.
    i. 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).
    ii. You can choose to have it collected one way and change your mind later by letting us know
    iii. The results will be shared with you by email 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…

- Do the first 4 things listed above AND
- For adults (18 years or older): Give us an email address to contact the adults so we can send them an invitation to participate
- For each child younger than 18 years of age:
    - Do online surveys:
        - at enrolment and against every 12 months (~2 minute per child)
        - every second week (~1 minute per child)
        - after each COVID-19 vaccination (~1 minute each dose)
        - illness/test questionnaires when children are tested for COVID-19 (~2 minutes)
        - once about your reasons to/not to vaccinate each child (~3 minutes)
        - once about your reasons to/not to re-vaccinate each child (~3 minutes)
    - Optional: if you and the child agree, collect blood samples (using a 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.
- 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.*

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 December 1, 2023. You may withdraw at any time by emailing COVID.study@sinaihealth.ca or calling 416-294-6383.

Are there any risks or benefits 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 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 their $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 each 10-week period will be eligible for the draw (1 certificate is drawn for every 500 biweekly reports in each period).
- 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. If you decide to withdraw from the study, information and specimens already gathered will not be destroyed.

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 (see https://simplesurvey.com/canadian-hosted-survey-software). 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.

When you give your consent, you keep all your legal rights relating to the research team members and the hospitals. The research team members and hospitals involved in this study have legal and professional duties to you and others taking part.

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 9AM and 5PM).

This study has been reviewed by the Michael Garron Hospital (MGH) Research Ethics Board (REB). The REB is independent of the researchers. If you have any concerns or questions about your rights or your experiences as a research participant, you may contact Dr. Sherry Rezaie, Chair of the MGH REB at 416-469-6580 ext. 3853, during business hours.

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)

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

OPTION #1: 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

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 about 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. 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.

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

By typing my name, I confirm that the above statements are correct and I consent to participate:

_____

A copy of your consent will be available on your study webpage (dashboard).