ST. MICHAEL'S
UNITY HEALTH TORONTO

Letter of Information and Consent to Participate in a Research Study
People working in hospitals

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

STUDY TEAM

Study investigator: Dr. Matthew Muller, Infection Prevention and Control, St. Michael's Hospital (416) 864-5568

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The principal investigator, co-investigators, and research staff do not have any conflicts of interest, financial or otherwise, related to this study or its outcome.

You are being asked to consider participating in this research study because you work in a Canadian healthcare setting.

All research is voluntary – you do not have to participate and you can withdraw at any time.

Before agreeing to take part in this study, it is important that you read the information in this research consent form. It includes details we think you need to know to decide if you wish to take part in this study. If you have any questions, ask a study team member.

If you choose to participate in this study, you will need to sign this Letter of Information and Consent form. You should not sign this form until you are sure you understand the information. You may also wish to discuss the study with others such as your family doctor, a family member, and/or a close friend.

What is the purpose of the study?

This observational research study is 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?

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/midwife with an independent practice who cares for patients 8 hours or more per week in the hospital
- are 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)

This study is being be conducted across Canada and will enroll 2460 healthcare workers and their household members including about 250 healthcare workers from St. Michael's campus.

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 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
g. When you are tested for COVID-19 (even if you have no symptoms) (~5 minutes);
h. When you have symptoms that might be COVID (even if you are not tested): (~5 minutes);

3) 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.

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

4) If you agree (optional), ask others in your household to participate (as detailed below)

Participants will be asked to provide blood samples to attempt to find out whether they have been exposed to COVID-19. We will do this through a blood test, called serology, that looks for antibodies to the virus. Antibodies are substances that the body makes to protect people from infections like COVID-19. Please note, having antibodies does not necessarily mean you have developed immunity to COVID-19; it simply means you likely have been exposed to the virus at some point.

The results of the antibody testing will be shared with all participants. However, this will take several months since the labs are very busy at this time.

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 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.
- If 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 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 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 risks or benefits 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 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 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

- 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 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).

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 or care. You may 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.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Rights as a Participant

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

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 located in Canada 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 Unity Health Toronto Research Ethics Board.

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 (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?

You can email the study staff at Sinai Health (the study's coordinating centre) COVID.study@sinaihealth.ca or call 416-294-6383 (weekdays between 9AM and 5PM) with any questions or comments.

The study protocol and consent form have been reviewed by the Unity Health Toronto Research Ethics Board. If you have any concerns about your rights as a research participant or your experiences while taking part in this study, contact Dr. David Mazer, chair of the Research Ethics Board at 416-864-6060 ext. 2557 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 Unity Health, St. Michael's campus 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 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 St. Michael's Hospital
☐ I will self-collect my blood (the study will mail collection kits to you)

OPTIONAL SECTIONS

OPTION #1: Invite people who live in my home to participate

☐ I live alone -or- I do not agree to invite others

or

Send me an email to share with people in my household who may be interested in participating in the study and are (*check all that apply*):

☐ 18 years or older
☐ 13-17 years old
☐ 8-12 years old

☐ I would like to enrol children younger than 8 years of age

For children 13-17 years old:

☐ I understand the study procedures for children AND I agree to the following child/children being a part of this study if they also consent to participate
☐ Optional: I agree to collect blood samples from this child when they join and again about every 6 months afterwards

1) Nickname* for child: _____ Age: _____ years

**Nicknames are to identify people with the same email address and to specify children in illness and bi-weekly reports, swabs, and blood samples. Please use nicknames you will remember but that do not make it easy for someone else to identify who they are.*

For children 8-12 years old:

☐ I am the parent or legal guardian of the following child or children who are 8-12 years of age AND I understand the study procedures for children AND I agree to the following child/children being a part of this study if they also give assent to participate
☐ Optional: I agree to collect blood samples from this child when they join and again about every 6 months afterwards

1) Nickname* for child: _____ Age: _____ years

**Nicknames are to identify people with the same email address and to specify children in illness and bi-weekly reports, swabs, and blood samples. Please use nicknames you will remember but that do not make it easy for someone else to identify who they are.*

For children younger than 8 years old:

☐ I am the parent or legal guardian of the following child or children who are younger than 8 years old AND I understand the study procedures for children AND I agree to the following child/children being a part of this study
☐ Optional: I agree to collect blood samples from this child when they join and again about every 6 months afterwards

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

**Nicknames are to identify people with the same email address and to specify children in illness and bi-weekly reports, swabs, and blood samples. Please use nicknames you will remember but that do not make it easy for someone else to identify who they are.*

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. No genetic testing will be conducted on your sample(s).

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