Information sheet and consent form for people working in hospitals

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

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Funders: Weston Foundation, Physicians' Services Inc., & 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 pandemic. This study is for research purposes. It is being be conducted across six Toronto-area hospitals and will enroll 800 healthcare workers and their household members.

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 physician, nurse practitioner, or midwife with an independent practice who cares for patients 8 hours or more per week in the institution
- 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 to assess your current risk factors (~15 minutes)
2) Short online surveys every week about whether you have had any symptoms (~2 minutes). Every fifth week, the survey will be a bit longer and ask about your exposure to ill people (~5-7 minutes)
3) When you are tested for COVID-19:
   a. Complete online illness reports to inform the study of your test results, symptoms, and contact with ill people (~5 minutes) and one every day you continue to have symptoms (~2 minutes);
   b. Submit a nasal swab to the study lab on the same day you are tested for COVID-19 (to assess viral load)
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 time)
6) At the end of the study, complete the "impact of events" and the "Kessler Psychological Distress" scale to assess the stress of working during the pandemic (~3-5 minutes)
7) If you agree (optional), provide blood samples:
   a. when you join, in 6 months, and at the end of the study;
   b. if you test positive for COVID-19, <u>once</u>, 30 days after your positive test;
   c. if you test positive for COVID-19, <u>every</u> 30 days after your positive test; and/or
   d. If you are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose
      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
8) If you agree (optional), ask others in your household to participate (as detailed below)

Participants will be asked to provide optional 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, which 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 6 things listed above AND
- Give us an email address to contact the adults so we can send them an invitation to participate
- Complete weekly 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: do online illness reports about the test results, symptoms, and contact with ill people – and - collect [or supervise the collection of] a nasal swab when they are tested (to assess viral load) (~ 5 minutes for the first and ~2 minutes for all reports)
- 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 - 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 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, 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; and/or
    - if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

Adults (18 years or older) are asked to do:

1) one baseline questionnaire (~5 to 15 minutes)
2) an online report every 5th week (~5-7 minutes)
3) when they are tested for COVID-19: do online illness report – and - submit a swab to the study lab on the same day they are tested (to assess viral load) (~ 5 minutes for the first and ~2 minutes for all reports)
4) if someone else in the home becomes ill, collect swabs and pledgets (small absorbent papers) 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.*
5) An online survey about their intent to be vaccinated against COVID-19 (~3 minutes)
6) An online questionnaire when (if) they are vaccinated against COVID-19 (~1 minute each time)
7) If they agree (optional): self-collect blood samples:
    a. at enrolment, in 6 months, and at the end of the study;
    b. if they test positive for COVID-19, once, 30 days after their positive test;
    c. if they test positive for COVID-19, every 30 days after their positive test; and/or
    d. if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

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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 be as long as 12 months.

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 volunteer for blood specimens to be taken, 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.
- A $20 electronic gift card is available for your participation. A $10 electronic gift card is available for children who participate. There is no direct other benefit to being in the study beyond having access to test results.

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. 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.

Who can I talk to if I have questions?

You can email the study staff at COVID.study@sinaihealth.ca or call 416-294-6383 (weekdays between 8AM and 6PM) 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)
- ☐ 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

OPTION #1: Blood

I agree to provide blood samples (*check all that you agree to*):

☐ when I join, in 6 months, and at the end of the study
☐ if I test positive for COVID-19, once, 30 days after my positive test
☐ if I test positive for COVID-19, every 30 days after my positive test
☐ if I am vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose
Or ☐ none of the above

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)

OPTION #2: 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 if they also agree ***(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
☐ if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose
Or ☐ none of the above

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

**Nicknames are to identify people with the same email address and to specify children in illness and 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 if they also agree ***(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
☐ if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose
Or ☐ none of the above

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

**Nicknames are to identify people with the same email address and to specify children in illness and 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 ***(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, <u>once</u>, 30 days after their positive test
☐ if they test positive for COVID-19, <u>every</u> 30 days after their positive test
☐ if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose
Or ☐ none of the above

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 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.*