HEALTHCARE WORKER PARTICIPANT INFORMATION SHEET

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

Locally Responsible Investigators:
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Sponsors: Weston Foundation, Physicians' Services Inc., Canadian Institutes of Health Research, & COVID-19 Immunity Task Force (Public Health Agency of Canada)

Introduction

You are being invited to take part in a research study about COVID-19 because you work in healthcare.

To decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with others.

Why is this research being done?

To reduce the burden of illness associated with COVID-19 by better informing both policy and individual decisions regarding its prevention. The findings will help characterize the clinical picture of the disease in healthy Canadians during the pandemic and answer questions regarding its management in hospitals and affiliated care centres and the households of healthcare workers.

What is the purpose of this study?

To better understand how many people develop COVID-19 infection, what the risk factors for infection are, 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?

We plan to enrol 300 healthcare workers from Hamilton Health Sciences (HHS) and St. Joseph's Healthcare Hamilton (SJHH). We will be enrolling 2460 healthcare workers from hospitals across Canada.

People working in an acute care, rehabilitation, or complex care hospital associated with HHS or SJHH are eligible if they:

- are 18 to 75 years old

- work anywhere in any hospital/centre for more than 20 hours per week
    - OR is a MD/NP/midwife with privileges who spends at least 8 hours per week in the hospital/centre
- 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 and every 12 months to assess possible sources of exposure (~15 minutes)
2) Short online surveys
    a. every second week (~2 minutes).
    b. One week in ten, the survey will be a bit longer and ask about your exposure to other ill people (~5-7 minutes)
    c. once about whether you intend to be vaccinated against COVID-19 (~3 minutes)
    d. once about reasons to/not to be re-vaccinated against COVID-19 (~3 minutes)
    e. after each COVID-19 vaccination (~1 minute each dose)
    f. every 6 months to assess your level of stress (~2 minutes)
    g. 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) Self-collect 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
    e. If you are not re-vaccinated: every 6 months after your last dose of vaccine
        i. 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). 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 (any age) who sleeps in the same dwelling as you 3 or more nights per week, on average, can take part.

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 who give you permission to include them in the study so we can send them an invitation to participate
- For each child younger than 18 years old
    - Do online surveys
        i. At enrolment and again every 12 months (~2 minutes per child)
        ii. Every second week (~1 minute per child)
        iii. Illness/test questionnaires when children are tested for COVID-19 (~2 minutes)

iv. After each COVID-19 vaccination (~1 minute each dose)
v. Once about your reasons to/not to vaccinate each child (~3 minutes each)
vi. Once about your reasons to/not to re-vaccinate each child (~3 minutes each)

- 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.

- 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.

Are there any risks to participating in the study?

- There are no physical risks to participating in the study. However, collecting a nasal swab or pledget may be uncomfortable
- The process of self-collecting blood is similar to how people with diabetes check their blood sugar and the heel stick given to newborns. It is occasionally necessary to stick a second finger. You may have a small amount of pain, bruising, or bleeding at the pick site.
- There is no cost to taking part in the study. All supplies and costs for shipping them to you are provided by the study.

Are there any benefits to participating in the study?

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.

It is important for you to know that you can choose not to take part in the study. This study is strictly for research purposes and choosing not to participate will not affect your employment in any way. If you choose to take part in this study, you will be told about any new information which might affect your willingness to continue to participate in this research.

What information will be kept private?

Your data will be kept confidential. You will not be named in any reports. Your name, address, email, and phone number will be transferred to the research team at Mount Sinai Hospital, who needs this information to ship supplies to you, send questionnaires/reminders, provide study information, and send test results. The information collected for the study, with identifiers removed, will be kept on secure servers at Canadian Web Hosting - 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 information that you enter at the end of this consent form (nicknames, email addresses, and your typed name) will also be stored at Mount Sinai Hospital.

For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board, the Mount Sinai Research Ethics Board, and this institution's and affiliated sites may consult your research data. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure.

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

Can participation in this study end early?

This study is expected to 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. If you volunteer to be in this study, you may withdraw at any time by contacting the study coordinator at covid.study@sinaihealth.ca or by phone at **416-294-6383** or, if long distance **1-888-307-3357** (weekdays 8am-6pm). Information provided up to the point where you withdraw will be kept unless you request that it be removed. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise that warrant doing so.

Will I be paid to participate in this study?

- When you complete your baseline questionnaire, K-10 questionnaires and the first five bi-weekly reports, you will receive an email offering you the choice of retailer for a $20 electronic gift card
- If you enroll children, once you complete their baseline and first five bi-weekly reports, you will receive an email offering them their choice of 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 each 10-week period will be eligible for the draws (1 certificate is drawn for every 500 bi-weekly reports in each period).

Will there be any costs?

Your participation in this research project will not involve any additional costs to you.

What happens if I have a research-related injury?

If you are injured as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

If I have any questions or problems, whom can I call?

If you have any questions about the research now or later, or if you think you have a research-related injury, please contact Dr. Brenda Coleman at **416-294-6383** or, if long distance: **1-888-307-3357** (weekdays between 9AM and 5PM).

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 for Hamilton Health Sciences including Hamilton General, Juravinski, McMaster Children's, St. Peter's, or West Lincoln Memorial Hospitals, McMaster University Medical, Juravinski Cancer, Ron Joyce Children's Health, Regional

Rehabilitation, or West End Clinic/Urgent Care Centres
☐ or I work for St. Joseph's Healthcare Hamilton including the Charlton, King, or West 5th campuses
☐ I work, on average, 20 hours per week for the hospital – OR – I am a physician or nurse practitioner who works, on average, 8 or more hours per week caring for ill patients
☐ I plan to be working for the hospital for at least the next 3 months (not planning to retire or go on leave)
☐ I do not meet one or more of these eligibility requirements

CONSENT STATEMENT

☐ I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that a copy of this consent form will be available on my online study profile/dashboard.

OPTIONAL SECTIONS

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 / children younger than 17 years old

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):

1) 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 for reports and samples.

1) 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 reports and samples

**An email will be sent to you with a link to *assent* forms for each child 7 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.

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at 905.521.2100 x 42013.