CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY
(Healthcare worker)

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

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

Introduction:
You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background/Purpose:
The purpose of this 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. It is also studying the effectiveness of COVID-19 vaccines, how antibody levels change over time, and the psychological impact of working during the pandemic. The information we learn from this study will be used to inform recommendations about the particular importance (or lack thereof) of protective measures for people working in healthcare as well as Canadian households.

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 at least 20 hours per week
  OR is a MD/NP with privileges who spends 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)

Study Visits and Procedures:
If you agree to participate you are asked to:

1) An online survey at enrolment and every 12 months to assess possible sources of exposure (~15 minutes)
2) Short online surveys
   - 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)
   - once about whether you intend to be vaccinated against COVID-19 (~3 minutes)
   - once about reasons to/not to be re-vaccinated against COVID-19 (~3 minutes)
   - after each COVID-19 vaccination (~1 minute each dose)

- every 6 months to assess your level of stress (~2 minutes)
- once at the end of the study to assess the psychological impact of working during the pandemic (~4 minutes)

3) Online illness/test questionnaire
   - when you are tested for COVID-19, even if you have no symptoms (~5 minutes)
   - when you have symptoms that might be COVID, even if you are not tested (~5 minutes)
4) Provide blood samples:
   - when you join;
   - 30 days after each positive test result for COVID-19
   - 30 and 180 days after each dose of COVID-19 vaccine
   - If you are not vaccinated: every 6 months after joining
   - 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 of self-collect it.
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 at least 3 nights per week, on average, is asked to participate.

If others in your home join the study, <u>you</u> are asked to…

1. Do the items listed above AND
2. 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
3. For each child younger than 18 years old
   a) Do online surveys
      - at enrollment and again every 12 months (~2 minutes per child)
      - every second week(~1 minute per child)
      - illness/test questionnaires when children are tested for COVID-19 (~2 minutes)
      - after each COVID-19 vaccination (~1 minute each dose)
      - 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)

   b) 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.
4. 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 local immune responses. *This is asked of ALL households where a person has COVID-19 and about 1 in 3 households where a person with symptoms submits a swab that tests negative for COVID-19.*

<u>How long will the study last?</u>

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.

<u>Risks and Benefits:</u>

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 the hospital, 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 learn how to reduce the risk of transmitting COVID-19.

Blood samples:
You can decide whether to have blood samples collected at the hospital (serum) or self-collect it (dried blood spots). 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.

Samples are identified by a unique study number that can only be linked to you by study staff. Serum samples will be processed and frozen while dried blood spot cards will be refrigerated until testing. The blood samples will be tested for SARS-CoV-2 proteins at the Lunenfeld-Tanenbaum Research Institute (Mount Sinai Hospital, Toronto). If you agree (see below), left-over serum may be shared with other researchers. All samples will be stored for up to 15 years at which time they will be discarded following hospital protocol for the destruction of samples.

Results of each blood test will be emailed to you when they become available. This takes several months.

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 to call you about study procedures, as needed. Your email address will be used by the electronic data capture application (SimpleSurvey.com) to send you study emails and link to your questionnaires for the duration of the study. SimpleSurvey will not share your email or any information about you with anyone outside of this study.

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 University Health Network 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 (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

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.

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

Withdrawal from the Study:
You may withdraw from the study at any time.

Costs and Reimbursement:
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 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

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.

Conflict of Interest:
The investigators declare no conflicts of interest.

Questions about the Study:
If you have any questions, concerns or would like to speak to the study team for any reason, please email the coordinator at covid.study@sinaihealth.ca or call **416-294-6383** between 9AM and 5PM.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be emailed a copy of this consent form.

The UHN research ethics board requires a verbal consent from all participants
Please call (416) 294-6383 between 9AM and 5PM to review this form with a research staff
If others in your home agree to participate, we can consent them during the same call or at another time.

CONSENT

This study has been explained to me and any questions I had have been answered.
I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

OPTIONAL SECTIONS

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

If adults included:
☐ I have asked other people living with me in my home to participate and they have agreed to receive an email inviting them to participate
#1) Household member's first name _____Household member's email address _____
#2) Household member's first name _____Household member's email address _____

If child/children included:

☐ I am the parent or legal guardian of children younger than 18 years of age and consent to their participation in the study (children will be required to provide verbal consent to study staff by phone if they are 12 to 17 years old)

#1) Child's age _____ Nickname for child: _____

☐ Yes, I agree to collect blood samples from this child when they join and again every 6 months afterwards, and 30 days after [if] they test positive for COVID-19

☐ No, I do not agree to collect blood samples from this child

#2) Child's age _____ Nickname for child: _____

☐ Yes, I agree to collect blood samples from this child when they join and again every 6 months afterwards, and 30 days after [if] they test positive for COVID-19

☐ No, I do not agree to collect blood samples from this child

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.

How do you prefer to collect blood samples for yourself?

- ☐ I will self-collect my blood (the study will mail the collection kits to you) → skip option #3
- ☐ I will have my blood collected at the lab at UHN (TGH, TWH, or PMCC) → please review option #3

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 and the de-identified data that accompanies them 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
- ☐ Not applicable, providing dried blood spot samples