Information Sheet and Consent Form

Study information

Title of Study:	Canadian COVID-19 Cohort Study (CCS): Study of the epidemiology of COVID-19 in Canadian healthcare workers
Principal investigator:	Dr. Robyn Harrison, MD, Provincial Communicable Disease Consultant, 780-735-7236
Co-Investigator:	Dr. Brenda Coleman, PhD, Sinai Health System, 647-267-2413

Why am I being asked to take part in this research study?

You are being asked to take part in a research study because you work in a hospital. 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 reason for doing the study?

To determine how many people develop COVID-19 infection and the risk factors for infection, to describe the changes in the carriage of antibodies against SARS-CoV-2 over time, the incidence of re-infection, the uptake of COVID-19 vaccines, and the psychological impact of working during the COVID-19 pandemic.

What will I be asked to do?

1) An online survey at enrolment and every 12 months to assess possible sources of exposure(~15 minutes)
2) Short online surveys
    i. 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)
    ii. once about whether you intend to be vaccinated against COVID-19 (~3 minutes)
    iii. once about reasons to/not to be re-vaccinated against COVID-19 (~3 minutes)
    iv. after each COVID-19 vaccination (~1 minute each dose)
    v. every 6 months to assess your level of stress (~2 minutes)
    vi. once at the end of the study to assess the psychological impact of working during the pandemic (~4 minutes)
3) Online illness/test questionnaires
    i. when you are tested for COVID-19, even if you have no symptoms (~5 minutes)
    ii. when you have symptoms that might be COVID, even if you are not tested (~ 5 minutes);
4) Self-collect blood samples
    i. when you join and every 6 months after that
    ii. 30 days after each positive test result for COVID-19,
    iii. 30 and 180 days after each dose of COVID-19 vaccine,
    iv. if you are not vaccinated: every 6 months after joining

v. if you are not re-vaccinated: every 6 months after your last dose of vaccine.

Self- collection is similar to how people with diabetes check their blood sugar: a finger prick and a collection card on which you place 5 blood drops. The results of the antibody tests will be shared with you within 6 months of the collection. If you have 2 samples due within a few weeks of one another (e.g., when you join and after a dose of vaccine) we will ask for only one.

How long will the study last?

The study will last until the end of the COVID-19 pandemic or December 1st 2023, whichever is shorter.

What are the risks and discomforts?

There are no medical risks to you from participating in this study, but you may feel anxiety when completing some of the study questionnaires. You do not have to answer any questions you do not want to.
You may have pain and minor bruising at the site of blood collection; it is occasionally necessary to prick a second finger.

What are the benefits to me?

You are not expected to get any benefit from being in this research study beyond having access to test results. However, information learned from this study may help us reduce the risk of spreading COVID-19.

What happens if I am injured because of this research?

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment at no additional cost to you. By signing this consent form you are not giving up any of your legal rights or releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

Do I have to take part in the study?

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect your employment status.

Can my participation in the study end early?

Your participation in the study may be stopped early, and without your consent, for reasons such as:

- The research team decides to stop the study
- The University of Alberta Research Ethics Board withdraws permission for this study to continue

What will it cost me to participate?

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.

Will I be paid to be in the research?

- You will not be paid to be in this research study. 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.

- A draw will be made every 10 weeks throughout the study for a $10 electronic gift card. All adult bi-weekly reports completed for that 10-week period will be eligible for the draws (1 certificate is drawn for every 500 biweekly reports in each period).

Privacy and Confidentiality

During this study we will be collecting information (or "study data") about you. We will use the data to help answer research questions and we will share (or "disclose") your information with others such as the study sponsor and other researchers. Below we describe in more detail how your data will be collected, stored, used and disclosed.

What data will we be collecting?

Although this research is being conducted by researchers from across Canada, all data you provide is being handled by research staff in Ontario (Sinai Health). Examples of the types of data we may collect includes your name, where you live, your ethnic background, your date of birth, your age, your health conditions, your health history, your medications 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 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.

How will the study data be stored?

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 Sinai Health System server (the central study site) and kept there for 10 years before being destroyed.

How will the study data be used?

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. These 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 will be able to look at my data?

The following people may look at your personal information to check that the information collected is correct: Representatives of the Sinai Health System Research Ethics Board, the University of Alberta auditors, and members of the Research Ethics Board.

No personal information will be shared outside the study except as required by law.

By signing this consent form you are saying it is ok for the study staff to collect, use and disclose information from your study data as described above.

If you would like to see the study data collected about you, please ask the study doctor. You will be able to look at the study data about you and you can ask for any mistakes to be corrected.

If you leave the study, we will not collect new information about you, but we will need to keep the data that we have already collected.

What if I have questions?

If you have any questions about the research now or later, please contact Dr. Brenda Coleman, PhD, at covid.study@sinaihealth.ca or call 1-888-307-3357 (weekdays between 7AM and 4PM GMT).

If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office is independent of the study investigators.

The study is being funded by the COVID-19 Immunity Task Force (CITF). The co-investigator is getting money from the study sponsor to cover the costs of doing this study. You are entitled to request any details concerning this compensation from the Principal Investigator.

ELIGIBILITY

Before you consent, it is important that we make sure that you are eligible to participate.

- ☐ I am 18-75 years old

I work at:

- ☐ Grey Nuns Community Hospital
- ☐ University of Alberta Hospital
- ☐ Royal Alexandra Hospital, or
- ☐ an acute care, rehabilitation, or complex care hospital in the Calgary Health Zone

- ☐ I work, on average, 20 hours per week for the hospital – OR – I am a physician, nurse practitioner, or midwife with privileges who works, on average, 8 hours per week caring for patients
- ☐ I plan to be working for at least the next 3 months

How do I indicate my agreement to be in the study?

By signing below, you understand:

- That you have read the above information and have had anything that you do not understand explained to you to your satisfaction;
- That you will be taking part in a research study;
- That you may freely leave the research study at any time;
- That you do not waive your legal rights by being in the study;
- That the legal and professional obligations of the investigators and involved institutions are not changed by your taking part in this study.

OPTIONAL CONSENT- Future Studies

In addition to the basic study, I agree to study staff from Sinai Health System contacting me by email or phone if there are other studies for which I might be eligible including those about:

COVID-19	Yes ☐	No ☐
other infectious diseases	Yes ☐	No ☐

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 my employment.