

**Canadian COVID-19 Cohort Study (CCS):  
Study of the epidemiology of COVID-19 in Canadian healthcare workers**

**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

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**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 to assess your current risk factors (about 15 minutes)
- 2) Short online surveys every week about whether you have had any symptoms (about 2 minutes)
  - One week in five, the survey will be longer to ask about your exposure to other ill people (about 5 minutes)
- 3) Every time you are tested for COVID-19, complete online illness reports to inform the study of your test results, symptoms, and contact with ill people (about 5 minutes) and one every day you continue to have symptoms (about 2 minutes per day); and
- 4) Self-collect blood samples
  - i. when you join, in 6 months, and at the end of the study
  - ii. every 30 days after you test positive (by NP swab) for COVID-19 (for up to one year)
  - iii. within 3 days before receiving a COVID-19 vaccine and again 30 days after your final doseSelf-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.

**How long will the study last?**

The study will last until the end of the COVID-19 pandemic or 12 months, 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 questionnaire and the first five 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 5 weeks throughout the study for a \$10 electronic gift card. All weekly reports completed within the previous 5 week period will be eligible for each draw.

#### **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. 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](mailto:covid.study@sinaihealth.ca) or call 416-294-6383 (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.

For Information Only

**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 either Grey Nuns Community Hospital or the University of Alberta Hospital
- I work, on average, 20 hours per week for the hospital – OR – I am a physician, nurse practitioner, or midwife who works, on average, 8 hours per week caring for patients
- I plan to be working for at least the next 3 months
- I do not meet one or more of these eligibility requirements

**CONSENT**

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Phone number: 780-735-7236

Co-Investigator: Dr. Brenda Coleman, PhD

Phone number: 647-267-2413

**CONSENT**

	<u>Yes</u>	<u>No</u>
Do you understand that you have been asked to be in a research study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you read and received a copy of the above Information Sheet? (a copy of this consent form will be available on your online study profile/dashboard)	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand the benefits and risks involved in taking part in this research study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had an opportunity to ask questions and discuss this study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that you are free to leave the study at any time, without having to give a reason and without affecting your employment?	<input type="checkbox"/>	<input type="checkbox"/>
Has the issue of confidentiality been explained to you?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand who will have access to your study records, including personally identifiable information?	<input type="checkbox"/>	<input type="checkbox"/>
<b>By checking this box and typing my name below, I am electronically signing this consent form</b>	<input type="checkbox"/>	<input type="checkbox"/>

**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.