



COVID-19 Cohort Study (CCS):

Study of the epidemiology of COVID-19 in healthcare workers and their households

Information Sheet and Consent Form Physicians, Healthcare Practitioners, and Clinic Staff

Study information

Study investigator: Dr. Allison McGeer, Microbiology & Infectious Diseases, (416) 586-3123

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 blood antibody levels change over time, and the psychological impact of working during the COVID-19 pandemic.

Who is being asked to participate?

Physicians, other healthcare practitioners, and staff working in private healthcare offices or clinics who:

- are 18 to 75 years old
- work at least 20 hours per week providing office-based care for patients in the greater Toronto area
- 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 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)
3. When you are tested for COVID-19, complete an online illness/test report to inform the study of your test results, symptoms, and contact with ill people (~5 minutes)
4. When you have symptoms that might be COVID (even if you are not tested): complete an online illness/test report (~5 minutes);
5. An online survey about whether you intend to be vaccinated against COVID-19 (~3 minutes)
6. An online questionnaire when (if) you are vaccinated against COVID-19 (~1 minute each dose)
7. An online questionnaire assessing your level of stress every 6 months (~2 minutes)
8. An online survey at the end of the study to assess the psychological impact of working during the pandemic (~4 minutes)
9. Self-collect blood samples:
 - a. when you join and every 6 months after that;
 - b. 30 days if/after you test positive for COVID-19, and
 - c. if you are vaccinated against COVID-19, prior to receiving your first dose and again 30 days after the final doseSelf-collection is similar to how people with diabetes check their blood sugar (with a finger prick and a collection card to put blood drops on);
The results will be shared with you after they are tested.
10. 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 3 or more 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 9 things listed above AND
- 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
- Complete bi-weekly symptom reports for children (<18 years old) in your home (about 1 minute per person)
- Do a very short online survey about each child (about 2 minutes per child)
- When children are tested for COVID-19: complete illness/test report (~2 minutes)
- 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.
- Optional: if you and they agree, collect blood samples from children (using finger prick and collection card)
 - when they join and again every 6 months, and 30 days after they test positive for COVID-19

How long will the study last?

The study will 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 September 30, 2023. You may withdraw at any time by emailing COVID.study@sinaihealth.ca or calling 416-294-6383.

Are there any benefits or risks to participating in the study?

- There are no physical risks to participating in the study.
- Collecting a nasal swab or pledget may be uncomfortable.
- Self-collection of blood is similar to how people with diabetes check their blood sugar and the heel stick given to newborns. It is occasionally necessary to prick a second finger. You may have a small amount of pain and bruising or bleeding at the prick site.
- There is no cost to taking part in the study. All blood collection kits, swabs and pledgets are provided by the study. The study pays to have supplies shipped to your home and returned to the lab.
- 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.

Expenses associated with participating in the 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 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.
- 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 draw

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 status. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying "pass".

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

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 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 Mount Sinai Hospital 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>

Who can I talk to if I have questions?

If you have any questions, concerns, or would like to speak to the study team for any reason, please call Dr. McGeer at 416-586-3123 or Dr. Coleman, PhD, at covid.study@sinaihealth.ca or call 647-267-2413 (weekdays between 8AM and 6PM).

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number at 416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

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 a physician's office/medical clinic located in the GTA
- I work more than 20 hours per week, on average, providing care for patients
- I plan to be working for at least 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

OPTIONAL SECTIONS

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 or children younger than 17 years old

Programmer: If adult(s) checked:

- No other adults live with me –or- I do not agree

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):

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 in bi-weekly symptom reports, swabs, and blood samples.

Programmer: If child/children checked:

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 (*check if you agree*):

- when they join and again every 6 months, and 30 days after they test positive for COVID-19

*Nicknames are used to identify people with the same email address and, if you agree to them joining the study, to identify children for illness and bi-weekly symptom reports, swabs, and blood samples

**An email will be sent to you with a link to assent forms for each child 12 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 other aspect of my employment.