Consent to participate in a research study

Title: Study of the epidemiology of COVID-19 in teachers and education workers in elementary and secondary schools in Ontario

Investigator: Dr. Brenda L. Coleman, PhD, Clinical Scientist, Sinai Health, Toronto, ON M5G 1X5
Co-investigators: Dr. Allison McGeer MD, Dr. Robert Maunder MD, Dr. Sharon Straus MD, Dr. Susan Bondy PhD
Sponsors: COVID-19 Immunity Task Force through the Public Health Agency of Canada and the Canadian Institutes of Health Research

Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits 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 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. Participation is voluntary.

What is the purpose of the study?

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

Who is being asked to participate?

People working for or with a school or school board in Ontario. This includes English or French, Catholic or non-denominational, publicly-funded or independent schools and school boards.
You are eligible if you:

- are 18 to 74 years old, inclusive
- work in any capacity for an elementary or secondary school or associated school board in Ontario
- work for 8 or more hours per week, on average, and
- plan to be available for at least the next 3 months (not retiring or going on leave, for example)

You can join the study whether you work online or on-site, whether you have or have not received your COVID-19 vaccine, and whether you have or have not previously tested positive for COVID-19
Because we require blood samples, you are **NOT** eligible to participate if you:

- have a bleeding disorder (e.g., hemophilia or Von Willebrand disease),
- have had chemotherapy with the past 4 weeks, or
- have had a bilateral mastectomy.

What do I need to do if I decide to participate?

1) A survey at enrolment to assess your current risk factors (it takes about 15 minutes) and update the survey every September (about 15 minutes each)
2) Short bi-weekly surveys (about 2 minutes each). One of every 6 bi-weekly surveys will be longer to ask about exposure to others (about 5 minutes each)
3) Every time you are tested for COVID-19, complete a report (about 5 minutes each)
4) Every time you have symptoms of a cold or influenza, complete a report (about 5 minutes each)
5) Complete a survey when/if you are vaccinated against COVID-19 (about 1 minute each dose)
6) Complete a stress/distress survey (K-10) every 26 weeks (about 3 minutes each)
7) Complete a survey at the end of the study to assess the psychological impact of working during the pandemic (about 4 minutes)
8) Self-collect blood spot samples a) when you join, b) every 26 weeks after joining, c) before receiving a COVID-19 vaccine dose(s), d) 30 days after each dose of vaccine, and e) 30 days after testing positive for COVID-19

Blood spot 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. You then mail it to the study office in a postage paid envelope.
Results of the blood tests will be emailed to you. This takes several months.

Study Requirements

Timing	Requirement
Start of study	• Consent • Baseline questionnaire • K-10 (stress) questionnaire • Vaccination questionnaire • Blood spot sample (kit is mailed to you)
When / if tested or ill	• Illness report • Blood spot sample 30 days after testing positive for COVID-19
When / if vaccinated	• Vaccination report • Blood spot samples: one before each dose and one 30 days after each dose of vaccine (mailed)
Every second week	• Bi-weekly questionnaire (reminder is emailed); 1 of 6 is a longer questionnaire
Every 26th week	• K-10 (stress) questionnaire • Blood spot sample (mailed)
Study end	• Impact of Events survey

How long will the study last?

The study will last until December 31, 2023

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

- You may have some very short-lived pain and minor bruising at the site of blood collection; it is occasionally necessary to prick a second finger. The K-10 questionnaire may prompt feelings of distress.
- There is no direct benefit to being in the study beyond having access to test results.

Expenses associated with participating in the study

- There is no cost to taking part in the study. All supplies are provided by the study.
- After you complete your baseline and K-10 questionnaires and we receive your first dried blood sample, you will be offered a $20 gift card from a list of retailers (e.g., coffee, gas, home products) that will be emailed to you.

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 by letting the study team know. Leaving the study will not affect 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.

By signing this form you do not give up any of your legal rights against the investigators, the COVID-19 Immunity Task Force, or involved institutions.

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 send supplies to you. 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 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 Sinai Health.

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. These data will be stored in a database at McGill University indefinitely. All identifying (personal) 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 contact Dr. Brenda Coleman, PhD, at ccs.2@sinaihealth.ca or call (437) 833-1745 or 1-888-307-3357 (weekdays 8 AM to 6 PM Eastern time).

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the Sinai Health 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 18-74 years old
- ☐ I work with/for a school or school board in Ontario
- ☐ I work, on average, 8 or more hours per week
- ☐ I plan to be working for at least the next 3 months

[Programmer note: people who do NOT check ALL of the criteria will not receive the Consent text, below]

CONSENT

- ☐ I have read this information sheet and I understand the study procedures
- ☐ I agree to be a part of the study

In addition to this study, I agree to:

☐ Study staff contacting me by email or telephone if there are other studies of infectious diseases for which I might be eligible. I understand that I may be asked if I am interested in participating in these studies and that I can decide, at that time, whether or not I wish to consider them. Participation in them is completely voluntary and will not affect my participation in this study.