

16-17 YEAR OLD HOUSEHOLD MEMBER OF HEALTHCARE WORKER PARTICIPANT INFORMATION SHEET

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

Study Investigators

Dr. Mark Loeb, Hamilton Health Sciences & McMaster University

Dr. Marek Smieja, St. Joseph's Healthcare Hamilton & McMaster University

Sponsors of the Study: Weston Foundation, Physicians' Services Inc., Canadian Institutes of Health Information, & COVID-19 Immunity Task Force (Public Health Agency of Canada)

Introduction

You are being invited to take part in a research study about COVID-19 because you live with someone who works in a hospital that is participating in the study.

To decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study. Once you understand the study, you will be asked to sign this form - if you wish to participate. Please take your time to make your decision. Feel free to discuss it with others.

Why is this research being done?

To reduce the burden of illness associated with COVID-19 by better informing both policy and individual decisions regarding its prevention. The findings will help characterize the clinical picture of the disease in healthy Canadians during the pandemic and answer questions regarding its management in hospitals and affiliated care centres and the households of healthcare workers.

What is the purpose of this study?

We would like to find out more about COVID-19. We want to know how often COVID-19 is spread between people who live together and whether there are germs or cells in our noses that protect us from COVID-19. We are also studying the effectiveness of COVID-19 vaccines and how antibody levels (in your blood) change over time.

Who is being asked to participate?

You are being asked to join the study because your parent has joined. If you join too, it will help us learn more about how COVID-19 spreads in people's homes.

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

If you agree to join this study, you will be asked to do two things.

- First, if someone in your home gets COVID-19 or a cold, we ask that you or your parents swab your

nose and put a small piece of paper (called a pledget) in your nose to collect germs and cells. We ask that you do this 4 or 5 times (about every second day).

- Second (optional): If you agree, we ask that you self-collect blood samples to see if your body made special cells to attack COVID-19. You have several choices about this option. You can agree to be in the study and not collect any blood samples. You can decide to collect several samples (about twice per year) or you can agree to collect the blood samples now and change your mind later.
- Your parent will answer questionnaires letting us know about your health status and whether you become ill with COVID-19 or another respiratory illness.

Collecting the blood is similar to how people with diabetes check their blood sugar levels: you prick your finger and put blood drops on a special card. The pin prick will cause pain for a short time and you may have some bruising. If you don't get enough blood the first time, some people need to prick a second finger.

Are there any risks to participating in the study?

The swabs and pledgets that go in your nose might bother you, but they will not hurt your nose.

If you agree to collect blood samples, it can cause a small amount of pain or bruising where you prick your finger.

Are there any benefits to participating in the study?

No, there is no direct benefit to being in the study. It may help other people if we learn how to stop the spread of COVID-19.

What information will be kept private?

Your data will be kept confidential. You will not be named in any reports. Your name, address, email, and phone number will be transferred to the research team at Mount Sinai Hospital, who needs this information to ship supplies to you, send questionnaires/reminders, provide study information and send test results.

The information collected for the study, with identifying information removed, will be kept on secure servers at Canadian Web Hosting 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 information that you enter at the end of this consent form (your typed name) will also be stored at Mount Sinai Hospital.

For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board, the Mount Sinai Research Ethics Board, and this institution's and affiliated sites may consult your research data. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure.

Do I have to be in this study?

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop. We are talking to your parents about the study and you should talk to them about it too.

Can participation in this study end early?

This study is expected to last until the end of this new virus spread in Ontario. This means that the study will be at least 4 months and may last until December 1, 2023. If you volunteer to be in this study, you may withdraw at any time by contacting the study coordinator at covid.study@sinaihealth.ca or by phone at **416-294-6383** or, if long distance: **1-888-307-3357** (weekdays 9am-5pm). Information provided up to the point where you withdraw will be kept unless you request that it be removed. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise that warrant doing so.

What happens after the study?

If you provided blood samples, we will send your parent/guardian a summary of your study results. All of the data we collect will be destroyed after 10 years.

If I have any questions or problems, whom can I call?

Before you say yes or no to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you have any questions about this study please feel free to ask Brenda Coleman at **416-294-6383** or, if long distance: **1-888-307-3357** (weekdays between 9AM and 5PM).

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 16 or 17 years of age
- I sleep in the same home 3 nights or more per week, on average, as someone who works at Hamilton Health Sciences, St Joseph's Healthcare Hamilton, or an associated rehab/complex care hospital
- Or I do not meet one or more of these requirements (statements)

CONSENT STATEMENT

- I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that a copy of this consent form will be available on my online study profile/dashboard.

- I agree to collect blood samples when I join and about every 6 months
- OR I do not want to collect blood samples

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at 905.521.2100 x 42013.