ADULT 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

Locally Responsible Investigators:
Dr. Mark Loeb (MD), Clinical Pathology, Hamilton Health Sciences & McMaster University
Dr. Marek Smieja (MD, PhD), Microbiology, St. Joseph's Healthcare Hamilton & McMaster University

Principal Investigators:
Dr. Allison McGeer (MD), Department of Microbiology, Sinai Health System & Lunenfeld-Tanenbaum Research Institute
Dr. Brenda Coleman (PhD), Infectious Disease Epidemiology Research Unit, Sinai Health System & University of Toronto
Dr. Dawn Bowdish (PhD), McMaster Immunology Research Centre, McMaster University

Sponsors: Weston Foundation, Physicians' Services Inc., Canadian Institutes of Health Research, & 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 healthcare.

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, which will be discussed with you. 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?

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 and how antibody levels (in your blood) change over time.

Who is being asked to participate?

We plan to enrol 300 healthcare workers from Hamilton Health Sciences (HHS) and St. Joseph's Healthcare Hamilton (SJHH) and 600 of their household members. To be eligible, you need to sleep in the same dwelling as the healthcare

worker 3 nights per week or more often.

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

1. An online survey at enrolment and every 12 months (~5-15 minutes)
2. Short online surveys
    a. every 2nd week (~2 minutes), 1 week in 10 will be a bit longer (~5-7 minutes)
    b. once about whether you intend to be vaccinated against COVID-19 (~3 minutes)
    c. once about whether you intend to be re-vaccinated against COVID-19 (~3 minutes)
    d. after each COVID-19 vaccination (~1 minute each dose)
3. Online illness/test questionnaire
    a. When you are tested for COVID-19, even if you have no symptoms (~3-5 minutes);
    b. When you have symptoms that might be COVID, even if you are not tested (~ 3-5 minutes);
4. When someone else in your home develops an acute respiratory illness: collect nasal swabs and pledgets (small absorbent papers you put in your nose) on Days 1, 3, 5, 7, & 10 to test for immune responses (what is different in the noses of people who get COVID-19 and those who do not). *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.*
5. If you agree (optional), self-collect blood samples:
    a. when you join;
    b. 30 days after each positive test result for COVID-19;
    c. 30 and 180 days after each dose of COVID-19;
    d. If you are not vaccinated: every 6 months after joining
    e. 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 (with a finger prick and a collection card to put blood drops on). The results will be shared with you after they are tested.

Are there any risks to participating in the study?

- There are no physical risks to participating in the study. However, collecting a nasal swab or pledget may be uncomfortable
- If you choose to volunteer to self-collect blood samples, you may have some pain and bruising at the prick site. It is occasionally necessary to prick a second finger.
- There is no cost to taking part in the study. All supplies and costs for shipping them to you are provided by the study.

Are there any benefits to participating in the study?

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.

It is important for you to know that you can choose not to take part in the study. This study is strictly for research purposes and choosing not to participate will not affect your employment in any way. If you choose to take part in this study, you will be told about any new information which might affect your willingness to continue to participate in this research.

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 call with test results. The information collected for the

study, with identifiers removed, will be kept on secure servers with Canadian Web Hosting using encryption software for up to 120 days after the end of the study (see https://simplesurvey.com/canadian-hosted-survey-software). 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 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.

Can participation in this study end early?

This study is expected to last until the end of this new virus spread in Ontario or the end of the study. 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 **1-888-307-3357** if long distance) (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.

Will I be paid to participate in this study?

- When you complete your baseline questionnaire and the first five bi-weekly reports, you will receive an email offering you the choice of 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 each 10-week period will be eligible for the draw

Will there be any costs?

Your participation in this research project will not involve any additional costs to you.

What happens if I have a research-related injury?

If you are injured as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

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

If you have any questions about the research now or later, or if you think you have a research-related injury, please contact Dr. Brenda Coleman at **416-294-6383** (or **1-888-307-3357** if long distance) (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 18 years of age or older

☐ I sleep in the same home (3+ nights per week, on average) as someone who works at Hamilton Health Sciences, St Joseph's Healthcare Hamilton, or an associated rehab/complex care hospital

☐ 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.

OPTIONAL SECTION

☐ I agree to collect blood samples as described above

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.