**CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY (Healthcare worker)**

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

**Investigator/Study Doctor:** Dr. Allison McGeer, Microbiology & Infectious Diseases, (416) 586-3123

**Contact Information:** Brenda Coleman, PhD, Infectious Disease Research, (647) 267-2413

**Sponsor:** Weston Foundation, Physicians' Services Inc., & COVID-19 Immunity Task Force

**Introduction:**
You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know 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 doctor or 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 including your friends, family, and family doctor. Participation in this study is voluntary.

**Background/Purpose**:
The purpose of this study is 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. It is also studying the effectiveness of COVID-19 vaccines, how antibody levels change over time, and the psychological impact of working during the pandemic. The information we learn from this study will be used to inform recommendations about the particular importance (or lack thereof) of protective measures for people working in healthcare as well as Canadian households.

**Who is being asked to participate:**
People working in an acute care, rehabilitation, or complex care hospital who:

- are 18 to 75 years old
- work anywhere in the hospital for more than 20 hours per week
  OR is a MD/NP with privileges who spends at least 8 hours per week in the hospital
- are 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)

**Study Visits and Procedures:**
If you agree to participate YOU are asked to:

1) An online survey at enrolment to assess your current risk factors (~15 minutes)
2) Short online surveys every week about whether you have had any symptoms (~2 minutes). One week in five, 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:
   a. Complete online illness reports to inform the study of your test results, symptoms, and contact with ill people (~5 minutes) and one every day you continue to have symptoms (~2 minutes); and
   b. Submit a nasal swab to the study lab on the same day you are tested for COVID-19 (to assess viral load)
4) An online survey about whether you intend to be vaccinated against COVID-19 (~3 minutes)

5) An online questionnaire when (if) you are vaccinated against COVID-19 (~1 minute each time)
6) If you agree (optional), provide blood samples:
    a. when you join, in 6 months, and at the end of the study;
    b. if you test positive for COVID-19, once, 30 days after your positive test;
    c. if you test positive for COVID-19, every 30 days after your positive test; and/or
    d. If you are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

    You can decide whether to have it collected at the hospital or self-collect it. Self-collection is similar to how people with diabetes check their blood sugar (with a finger prick and a collection card to put 5 blood drops on). You can choose to have it collected one way and change your mind later by letting us know

    Results of the blood tests will be emailed to you several weeks after your first sample arrives at the study office, after your final dose of vaccine (if you are vaccinated), and after your final sample at the end of the study (which will include all results of all samples submitted).
7) If you agree (optional), ask others in your household to participate (as detailed below)

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**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 at least 3 nights per week, on average, is asked to participate.

**If others in your home join the study, you are asked to…**

- Do the things listed above AND
- Give us an email address to contact the adults who give you permission to share their email address with the study so we can send them an invitation to participate
- Complete weekly symptom reports for everyone 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: do online illness reports – and - collect [or supervise the collection of] a nasal swab when they are tested (to assess viral load) (~ 5 minutes for the first and ~2 minutes for all reports)
- 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 local immune responses - to see if there are differences in the microbes in the noses of people who get COVID-19 and those who don't. *This is asked of ALL households where a person has COVID-19 and about 1 in 3 households where a person with symptoms submits a swab that tests negative for COVID-19.*
- Optional: if you and they agree, collect blood samples from children (using a finger prick and collection card):
    - when they join, in 6 months, and at the end of the study;
    - if they test positive for COVID-19, once, 30 days after their positive test;
    - if they test positive for COVID-19, every 30 days after their positive test; and/or
    - if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

**If others in your home join the study, the adults (18 years or older) are asked to do…**

1) one baseline questionnaire (~5 to 15 minutes)
2) an online report every 5th week (~5-7 minutes)
3) when they are tested for COVID-19: do online illness reports – and - submit a swab to the study lab on the same day they are tested (to assess viral load) (~ 5 minutes for the first and ~2 minutes for all reports)
4) when someone else in the home becomes ill, collect swabs and pledgets (small absorbent papers) 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 that tests negative for COVID-19.*
5) An online survey about their intent to be vaccinated against COVID-19 (~3 minutes)

6) An online questionnaire when (if) they are vaccinated against COVID-19 (~1 minute each time)
7) If they agree (optional), self-collect blood samples:
    a. at enrolment, in 6 months, and at the end of the study;
    a. if they test positive for COVID-19, once, 30 days after their positive test;
    b. if they test positive for COVID-19, every 30 days after their positive test; and/or
    c. if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

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**Risks and Benefits:**
There are no physical risks to participating in the study. Collecting a nasal swab or pledget may be uncomfortable. If you choose to volunteer for blood specimens to be taken, you may have some pain and bruising at the site. If blood is self-collected, it is occasionally necessary to prick a second finger. You may have a small amount of pain or bruising at the prick site.

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 learn how to reduce the risk of transmitting COVID-19

**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 University Health Network Research Ethics Board or Health Canada.

No personal information will be shared outside the study except as required by law.

**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.

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

**Withdrawal from the Study:**
You may withdraw from the study at any time.

**Costs and Reimbursement:**
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.
A $20 electronic gift card is available for your participation. A $10 electronic gift card is available for children who participate.

**Rights as a Participant:**
If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**Conflict of Interest:**
The investigators declare no conflicts of interest.

**Questions about the Study:**
If you have any questions, concerns or would like to speak to the study team for any reason, please email the coordinator at covid.study@sinaihealth.ca or call 416-294-6383 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 University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be emailed a copy of this consent form.

**[ONLINE ONLY:]**
**The UHN research ethics board requires a verbal consent from all participants**
**Please call (416) 294-6383 between 8AM and 6PM to review this form with a research staff**
**If others in your home agree to participate, we can consent them during the same call or at another time.**

**Consent:**
This study has been explained to me and any questions I had have been answered.
I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

OPTIONAL
**OPTION #1: Blood**
**I agree to provide blood samples (*check all that you agree to*):**
☐ when I join, in 6 months, and at the end of the study
☐ if I test positive for COVID-19, once, 30 days after my positive test
☐ if I test positive for COVID-19, every 30 days after my positive test
☐ if I am vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose
Or ☐ none of the above

**How do you prefer to collect blood samples for yourself?**
☐ I will have my blood collected at the lab at UHN (either TWH, TGH, or PMCC)
☐ I will self-collect my blood

**OPTION #2: Invite people who live in my home to participate**
☐ I agree to having others in my household participate in this study
☐ adult(s) 18 years of age or older
☐ child / children younger than 17 years old

**If adults checked:**
☐ I have asked other people living with me in my home to participate and they have agreed to receive an email inviting them to participate

Household member's first name _____
Household member's email address _____

**If child/children checked:**

☐ I am the parent or legal guardian of children younger than 18 years of age and consent to their participation in the study (children will be required to provide verbal consent to study staff by phone if they are 12 to 17 years old)

Child's age _____ Nickname for child: _____

OPTIONAL:

**I agree to collect blood samples from this child *(check all that you agree to)*:**

☐ when they join, in 6 months, and at the end of the study

☐ if they test positive for COVID-19, once, 30 days after their positive test

☐ if they test positive for COVID-19, every 30 days after their positive test

☐ if they are vaccinated against COVID-19, prior to receiving each dose and again 28 days after the final dose

Or ☐ none of the above