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***Baycrest Hospital***

*Halton Healthcare*

*Headwaters Healthcare Centre*

*Humber River Hospital*

*Joseph Brant Hospital*

*Lakeridge Health*

*Mackenzie Health*

*Markham Stouffville Hospital*

*Mount Sinai Hospital*

*North York General Hospital*

*Scarborough Health Network*

*Sinai Health System*

*Southlake Regional Health Centre*

*St. Joseph’s Healthcare-Hamilton*

*St. Michael’s Hospital*

*Sunnybrook Health Sciences*

*Toronto East Health Network*

*Trillium Health Partners*

*Unity Health Toronto*

*University Health Network*

*William Osler Health System*

*Women’s College Hospital*

[**CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY**](file://C:\Users\amcgeer\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\Users\amcgeer\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\AppData\Local\Microsoft\Windows\AppData\Local\Microsoft\Windows\Documents%20and%20Settings\mmekhail\Local%20Settings\Temporary%20Internet%20Files\Content.Outlook\K0Y83DNF\Consent%20Form%20Guidance%20Document.doc#DT)

**Study Title:** RECOVER-COVID: A prospective cohort study to identify predictors of

immune responses and re-infection for COVID-19

**Study Doctors:** Dr. Allison McGeer, Sinai Health System

Dr. Samir Mubareka, Sunnybrook Health Sciences Centre

Dr. Christopher Kandel, University of Toronto

Dr. Eric Coomes, University of Toronto

Dr. Jeff Powis, Toronto East Health Network

Dr. Wayne Gold, University Health Network

Dr. Rima Styra, University Health Network

Dr. Kevin Katz, North York General Hospital

Dr. Tony Mazzulli, Sinai Health System

Dr. Anne Claude Gingras, Sinai Health System

**Study sponsor:** Sinai Health System

**Study funder:**  Pfizer, Inc.

**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 the 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. Participation in this study is voluntary.

**Purpose**:

The purpose of this study is to better understand whether people who have had COVID-19 can be re-infected, what factors are associated with risk of re-infection, and whether different virus variants are more likely to cause infection. We are also interested in how well different vaccines work against COVID-19, particularly against new variants, and whether the amount of antibody people make and how long it lasts is associated with protection against new infection. Finally, we are also interested in how COVID-19 and living through the pandemic has impacted well-being. You are being asked to participate because you had COVID-19 between January and June of 2020, or because you were tested for COVID-19 at a study hospital during this time period but did not have COVID-19.

**Study Procedures:**

If you agree participate in this study, you will have to have access to the internet and to email, and to be willing to complete surveys on line and to receive emails once every 2 weeks for one year. You will be asked to:

* Log into the study site to complete an on-line questionnaire about:
  + your health and any medications you are taking
  + your history of COVID-19, COVID-19 testing and vaccination
  + your past and current activities and adherence to public health measures during the pandemic
  + any measures you have taken to protect yourself from COVID-19
  + your quality of life, stress and anxiety

This questionnaire will take about 30 minutes altogether (it does not have to be done all at once). You can do the questionnaire by telephone if you prefer.

* Log in to the site over the next 12 months to document :
  + Any positive tests for COVID-19, and to record any symptoms you have and what care you get if you test positive for COVID-19
  + Any doses of a COVID-19 vaccine, including the name/type of vaccine, and any adverse events that require medical care within the month after vaccination
  + Any known exposure you have to a person with COVID-19, even if you don’t get sick
* Allow study staff to confirm your COVID-19 vaccination status by contacting your vaccine provider
* Agree to receive emails every 2 weeks for a year in which you will be asked to answer some questions about your activities and adherence to public health measures, and be reminded about reporting COVID, COVID vaccination and adverse events to a COVID vaccine (this will take 1-2minutes each 2 weeks)
* Do a finger prick and collect 5 drops of blood (about 1/50th of a teaspoon), or visit a hospital or your nearest LIfelabs blood drawing site to have a blood sample (2 teaspoons, or 10 mls) at the following times:
  + Now as well as6 and 12 months from now
  + At the time you are diagnosed with COVID-19 (if this happens), and 4-6 weeks later (see below)
  + If you find that you are exposed to another person with COVID-19
  + 2-4 weeks after you complete your vaccination course (usually 2 doses of a vaccine)

A finger prick is the same technique that people with diabetes use to measure their blood sugar: it uses a very short needle to automatically poke your finger so that it bleeds a small amount. The blood drops are collected on a piece of filter paper. Antibodies against COVID-19 are then measured in this blood.

If you decide to have serum drawn at the hospital or at Lifelabs, you will be given $25 to cover the cost of travel/parking.

* If you get COVID, during the study period
  + Collect a saliva specimen and send it to the study office
  + Allow study staff to review your medical chart if you were admitted to the hospital with COVID-19
  + Allow the study staff to use any remaining blood samples (if you were admitted to the hospital with COVID-19) in order to perform viral sequencing
  + Collect (as per above) two blood samples – one at diagnosis and one 4-6 weeks later
  + If your COVID-19 is a re-infection or an infection after vaccination, you will be asked to have a larger volume (80 mls or 16 teaspoons) of blood drawn at the time of infection, and 4 weeks later. Because you will be in isolation if you have COVID-19, someone will come to your home to draw the first blood sample. You will receive a $25 honorarium for each sample of 80mls submitted.
  + You can decide at the time whether or not you agree to these extra blood samples.
* Complete a second on-line questionnaire about your quality of life 12 months from now.
* You will also be asked whether you agree to be contacted about future studies.

You can agree to be part of the study now, but decline to do any of these parts of the study at any time. You can also agree to be part of the study, but change your mind at any time and withdraw from the study. If you let us know that you no longer wish to receive them, we will stop sending you email reminders.

Table of study activities

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study activities** | | | | | | | | | |
| Regular activities over the next 12 months | | | When/If you get vaccinated | | When/If you get COVID for the first time before vaccination | | When/If you get COVID for a second time or after vaccination | | Exposure to COVID |
| START | 6 Months | 12 months | 1 DAY PRE 1st DOSE | 2-4 WEEKS POST 2nd DOSE | DATE COVID TEST  +ve | 4-6 WEEK POST | DATE COVID TEST +ve | 4-6 WEEK POST | DATE OF BEING INFORMED |
|  |  |  |  |  | Nasal swab and saliva |  | Nasal swab and saliva |  | Nasal swab and saliva |
| finger prick  OR  10ml blood | finger prick  OR  10ml blood | finger prick  OR  10ml blood | finger prick  OR  10ml blood | finger prick  OR  10ml blood | finger prick  OR  10ml blood |  | finger prick  OR 10ml blood  OR 80ml blood at each time point | | finger prick  OR  10ml blood |
| Baseline questionnaire |  | Quality of life questionnaire | Complete questionnaire: vaccine type and dose (on-line) | | Complete questionnaire about illness | | Complete questionnaire about illness | |  |
|  | Respond to email q2weeks  Brief questions about public health measures every 3 months | |  | |  |  |  |  |  |

**Risks and Benefits:**

Having your blood drawn is painful, and may be associated with some bleeding and bruising at the site. Finger sticks are also painful, although less so than having blood drawn. Nasal swabs may also cause discomfort. There are no other physical risks to taking part in this study and no risk to having the samples stored in the research lab. Some participants may find the questionnaires bring up feelings of anxiety or sadness. The website has links to mental health resources that you may find useful (https://www.camh.ca/en/health-info/mental-health-and-covid-19). You may also contact that study coordinator at any time if you need support or help. You will receive nodirect benefit from being in this study. We hope that the results may help other people in the future.

**Confidentiality:**

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study except as required by law. You will be identified with a study number only, which will be used on all study documents and laboratory samples. Identifying information collected for the purpose of contacting you will be kept separate from your study files and will be destroyed once the data collection and analysis are finished. No names or identifying information will be used in any publication or presentations.

Because SARS-Cov-2 is a new virus, many researchers will be working on understanding this infection, and on developing tests to diagnose this infection, vaccines, and treatments. Having enough different samples is important for these studies. For these reasons, we are asking for permission to share your study samples and information about your illness with other researchers at universities, companies, and public health laboratories. A group of study doctors and the research ethics board at Sinai Health System will make sure that these requests make the best use of your samples, and that they are only used in research related to COVID-19 or other respiratory infections. If parts of your samples, and/or your data are shared, they will be de-identified; that is, it will not be possible for researchers outside this study to find out who you are, or to link your sample or data to you. If the information is transferred outside of Canada, it will be subject to the laws of that country where it is stored, which may not be as strict as Canadian laws. However, only de-identified data and samples will be transferred. Samples may be stored for up to 10 years.

In Ontario, infections due to this novel coronavirus are reportable. This means that, if you agree to join the study, the study researchers are required by law to report the infection to the public health department, even though your doctor may have already reported it.

It is important to remember that email is not a secure form of communication. Email messages may be forged, forwarded, kept indefinitely, or seen by others using the internet, and should not be used to convey information you want to keep in confidence.

Representatives of the hospital including the Research Ethics Board, and the funder (Pfizer) may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines.

**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 care. You can refuse to answer any question in the questionnaire you do not want to answer by simply not filling it out. If you leave the study, the information that was collected before you left the study will still be used to help answer the research question, unless you tell us to remove it. No new information will be collected.

**Conflict of Interest :**

Both the investigators and the study funder (Pfizer) have an interest in completing this study. Their interests should not influence a decision to participate and you should not feel pressured to do so.

**Questions about the Study:**

If you have any questions, concerns or would like to speak to the study team for any reason, please call Dr. Allison McGeer, the primary investigator, or the research coordinator, at 416-586-4800 ext. 2767. If you have any questions about your rights as a research participant or have concerns about this study, you may call the Mount Sinai Hospital Research Ethics Board at 416-586-4875. The research ethics board is a group of people who oversee the ethical conduct of research studies. The research ethics board is not part of the study team. Everything that you discuss will be kept confidential.

**In Case You are Harmed in the Study:** If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

**Expenses Associated with Participating in the Study:**You will not be compensated for your participation in this study. If however you are required to have bloodwork taken at the hospital or at lifelabs, you will be provided with $25 to cover the cost of travel/parking. If you develop COVID-19 a second time, or after vaccination and agree to have 80mls of blood drawn, you will receive an additional $25 to compensate you for the time required to arrange a home visit and because of the additional blood draw volume.

**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 the following parts of this study:

(Please circle and initial the appropriate box below indicating your choices):

|  |  |  |
| --- | --- | --- |
|  | **Circle& initial boxes** | |
| 1. I understand that I may choose to send in finger prick blood samples (dried blood spots, DBS), or have blood drawn for serum (serum). I understand that I may change my mind at each time I am due to send a sample by notifying the study | **DBS** | **Serum** |
| 1. I agree that if I develop a second COVID19 infection, or a COVID infection after vaccination, I will have a larger volume blood sample obtained at a home visit for studies of T cell immunity. I understand that I can change my mind about this at the time of infection | **YES** | **NO** |
| 1. I agree that the study can contact me about participating in future research about COVID-19 | **YES** | **NO** |
| 1. I would like to have the results of my antibody tests shared with me at the end of the study via email. I understand that email messages may be forged, forwarded, kept indefinitely, or seen by others using the internet, and should not be used to convey sensitive information | **YES** | **NO** |

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Print Study Participant’s Name Signature Date

*My signature means that I have explained the study to the participant named above. I have answered all questions.*

Print Name of Person Obtaining Consent Signature Date