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Mackenzie Health
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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 TO PARTICIPATE IN A RESEARCH STUDY - STAFF/CAREGIVER

Study Title: Immunogenicity of COVID-19 Vaccines in Long Term Care

Study Doctors: Dr. Anne Claude Gingras, Sinai Health System
Dr. Allison McGeer, Sinai Health System
Dr. Mario Ostrowski, Unity Health
Dr. Jen Gommerman, University of Toronto
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Funding Source: Canadian 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 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 the body's immune response to COVID-19, including which factors protect against COVID-19 infection, and how vaccines work against COVID-19, an infection due to a new coronavirus. We wish to describe how much antibody people make when they are vaccinated against the virus that causes COVID-19, and how long the antibody lasts. We are also interested in whether people who have had COVID-19 before make more antibody, or have antibody that lasts longer and whether residents of long term care homes make less antibody than other adults, which does not last as long. You are being asked to participate because you work, or are an essential caregiver at a long term care home in south central Ontario. You are eligible to be part of the study if you are planning to be vaccinated against COVID-19.

Study Procedures:

If you agree to participate in this study, you will be asked to:

1. Allow research staff to ask you a few questions about yourself, any medical conditions you may have and any regular medications you are taking (about 5 minutes), whether or not you have had COVID-19 and when, and which COVID vaccine you have received or will receive and when.
2. Submit blood samples. These blood samples will be collected 3 or 4 times during the study. There are two types of participation; you can participate in the one you prefer:

Option 1 (For LTCH staff only):

a) Have samples of venous blood taken (25 mls) before or up to 7 days after your first dose of the vaccine if you have already received it, and at 12 months after your second vaccine dose, and 5 mls of blood taken 2-4 weeks and 6 months after your second dose. You can have blood drawn on site at your LTC home or at a Lifelabs center convenient to you. If you received your first dose of vaccine more than 7 days ago, you may still participate. You will miss the first blood and saliva collection, and be asked to have 25 mls of blood drawn 2-4 weeks after your second dose of vaccine.

b) Provide a saliva sample via salivette (i.e., a swab that you hold in your mouth) at the same time as you provide blood samples.

STUDY SCHEDULE – OPTION 1

Data Collection Measure	**Baseline (i.e., pre-vaccine or up to 7 days post-vaccine)**	**14-28 days (2-4 weeks) post 2nd dose of vaccine**	**6 months post 2nd dose of vaccine**	**12 months post 2nd dose of vaccine**
Blood draw	• 3 tubes total	• 1 tube total	• 1 tube total	• 3 tubes total
Saliva (salivette tube)	• 1 saliva sample via salivette	• 1 saliva sample via salivette	• 1 saliva sample via salivette	• 1 saliva sample via salivette
Data collection	Baseline questionnaire	Covid infection status	Covid infection status	Covid infection status

Option 2 (For LTCH staff and care givers):

a). Do your own finger prick, and collect 5 drops of blood (about 1/50th of a teaspoon) at 4 times: just before or shortly after you get your first vaccine dose, just before you get your second, 2 weeks after you get your second, and 4 months after you get your second. 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

b). If you choose this option, you will also be asked if you would be willing to have one of the blood samples be a regular blood draw (5 mls or 1 teaspoon). For participants who agree to have the blood drawn, the dried blood spot to be collected at 2 weeks post vaccine -will not be necessary.

STUDY SCHEDULE – OPTION 2

	Baseline (i.e., 14 days before to 14 days after 1st dose of vaccine)	**Immediately before 2nd dose of vaccine**	**14 days post 2nd dose of vaccine**	**4 months post 2nd dose of vaccine**
Dried blood spot (DBS)	• 1 DBS sample	• 1 DBS sample	• 1 DBS sample	• 1 DBS sample
Blood draw			• 1 tube total *(If you complete blood draw DBS at this time point will not be necessary)*	
Data collection	Baseline questionnaire	Covid infection status	Covid infection status	Covid infection status

3. Call the study staff to let them know if you test positive for COVID-19 during the study, and allow study staff to ask you about your COVID-19 infection status each time you are contacted to arrange sample collection, and call you at the end of the study to confirm whether or not you have been infected.

4. Allow the study staff to contact you after the study is over to ask if you are willing to be contacted about future studies of COVID-19.

You can agree to help with all or only some of these things at the end of this form. You can also agree to be part of the study now, but change your mind later. You can also choose at the end of this consent form whether or not you wish to know the results of your antibody tests.

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). There are no other physical risks to taking part in this study and no risk to having the samples stored in the research lab. You will receive no direct benefit from being in this study. We hope that the results may help other patients 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.. Any information or laboratory samples collected for the study will be identified with a unique study number only. 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, with the exception of your professional role, will be shared or used in any publication or presentations that result from this research. Anonymized data will be shared with the study funders, the Covid-19 Canadian Immunity Task Force (CITF), according to their data sharing protocol, so it can be combined with data from other sites and studies. Additionally, other researchers can request anonymized data from the CITF data Access Committee.

Representatives of the hospital including the Research Ethics Board 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 employment in any way. During the study interview, you may refuse to answer any question you do not want to answer by just saying “pass”. 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.

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 at 416-586-4800 ext. 2761, or the research coordinator, at 416-586-4800 ext. 2767. if you choose to use email to communicate with study staff, it is not considered a secure form of communication and should not be used to convey sensitive information.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.

Conflict of Interest :

The Canadian Immunity Task Force, the sponsor of this study, will pay the hospital and researcher for the costs of doing this study. All of these people have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study.

Expenses Associated with Participating in the Study:

You will not have to pay for any of the procedures involved with this study If you chose to participate by providing venous blood samples you will receive $50 as compensation for your time and travel to provide each sample. With permission of the participant, their name and address may be shared to request cheques for compensation of time and travel associated with collection of blood samples.

STATEMENT OF CONSENT TO PARTICIPATE IN A RESEARCH STUDY - STAFF/CAREGIVER

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 participation in this study and specifically the following (Please circle and initial the appropriate box below indicating your choices):

	circle & initial boxes:	
1. Submitting following samples :		
Option 1*a:* Providing a sample of blood via a venous blood draw at 4 different times over 1 year	**YES**	**NO**
Option 1*b:* Providing a saliva sample via salivette at 4 different times (at the same time as you provide venous blood samples).	**YES**	**NO**
***Option 2*a.**Having a finger prick to obtain 5 drops of blood at 4 different times	**YES**	**NO**
Option 2*b:* Having a blood sample taken 2 weeks after the second dose of the vaccine in place of the fingerstick on that occasion	**YES**	**NO**
2. Permission to contact me after this study is over. I agree that the study can contact me about participating in future research about COVID-19	**YES**	**NO**
3. I would like to have the results of my antibody tests shared with me at the end of the study	**YES**	**NO**

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 _____