Sinai Health | Lunenfeld-Tanenbaum Research Institute

Mount Sinai Hospital
Joseph & Wolf Lebovic Health Complex

Bridgepoint Active Healthcare

TCPS

OICR
Ontario Institute for Cancer Research

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title	SHAWL-1 (Stay-Healthy-At-Work) Study: Occurrence of serological positivity of SARS-CoV-2 reactive antibodies and of salivary SARS-CoV-2 RNA in the LTRI/Sinai and OICR workforce over time
Investigator	Dr. Pamela Goodwin, Clinical PI
Co-Investigators	Dr. Anne-Claude Gingras (Principal Investigator and Lead Scientist), Dr. Rod Bremner, Dr. Jeff Wrana, Dr. Jim Woodgett, Dr. Rita Kandel, Dr. Tony Mazzulli, Dr. Keith Jarvi, Dr. Steven Gallinger
24 Hour Phone Number	Linda Bennett (Study Co-ordinator) 416 586 4800 x 2426 or cell: 647-885-0952 Locating: 416-586-5133 (ask for Dr. Goodwin)
Sponsor	Sinai Health & LTRI (Sinai Health Foundation funding)

Introduction

You are being invited to participate in a research study because you work at, or have a relationship with, the Lunenfeld-Tanenbaum Research Institute (LTRI) and/or Sinai Health or the Ontario Institute for Cancer Research (OICR). Please read this explanation about the study and its risks and benefits 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. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect your employment status or academic standing at LTRI/Sinai Health/OICR or your relationship with, or care at, Sinai Health.

Background and Purpose

This research is being conducted to develop safe and efficient approaches to testing for antibodies to SARS-CoV-2 (the virus that causes COVID-19) in the blood and for the presence of the SARS-CoV-2 virus in saliva. Testing blood and saliva at regular intervals over six months will help us understand how many study participants may have been infected before the study began and how many become infected over time.

The presence of antibodies in blood likely reflects past COVID 19 infection, even if you have had no symptoms of COVID-19. We do not know if the presence of antibodies means you are immune to future COVID-19 illness. Because antibodies may only be present for a short period of time after infection, the absence of antibodies does not mean you do not have current or past COVID-19 infection.

The presence of virus in saliva may indicate current infection - you will be informed of this result and given advice for further testing and management.

Study Design

The study is being coordinated by the LTRI. We will include about 500 individuals who work at, or have a relationship with, the LTRI/Sinai Health or OICR. We will complete enrollment in ~2-3 months and each participant will be involved in study activities for six months.

To be eligible to donate for this study, you must:

- Be healthy with no current symptoms of COVID-19 infection

  OR

- If you have tested positive for COVID-19 via a nose or mouth swab, the positive test was at least 2 weeks ago and you have now recovered. If you are an employee of LTRI/Sinai Health or OICR, you have been declared free to return to work by your employer's Occupational Health and Safety personnel.

Study Visits and Procedures

You will receive an email inviting you to participate in the study. The email will include a link to the study information page and a link to the study participants' web platform. Take as much time as you need to think about whether or not you wish to participate in the study. You will be able to join the study until 500 participants have been enrolled.

Specimen and Data Collection

To begin participation in the study you will register in the study website. You will be able to review and complete the eligibility form to see if you qualify for the study and to access the Informed Consent Form. If you decide to proceed with the study, you will sign the consent form electronically. Once the consent form is signed, the web platform will provide you with your unique study identification number. Please note this number. All specimens, assay results and questionnaires will be identified using this study number.

After you consent, you will be scheduled (by email) to meet briefly with study personnel to affirm your electronic consent and to receive the initial package of materials needed to collect blood and saliva specimens, as well as paper copies of instructions for specimen collection. Bring your study identification number to this meeting. You will

receive emails to remind you to complete questionnaires and collect specific specimens throughout the study.

Self-collected Blood Samples (Baseline, Weeks 8, 16, 24)

The study team will provide you with your specimen collection and drop-off schedule. Although self-collection of blood is strongly encouraged, venipuncture will be offered if you are unwilling/unable to perform self-collection at any/all time points.

You will be instructed to review a short video showing you how to collect blood. (https://drive.google.com/file/d/1R7vvMRwhBq05hfqRLsgYmEM3CidvL0Di/view?usp=sharing)

Instructions for collection are also provided with specimen collection kits. Once blood is collected you will deposit the specimen into a designated drop off point on the day of specimen collection.

If you opt for venipuncture, visits will be scheduled (via email) with a trained phlebotomist at the LTRI Prosserman Centre at 60 Murray St. or at the MSH Laboratory (600 University Ave., 4th floor) for a 7.5 ml venous blood draw. You will need to bring one blood specimen label to this appointment.

In addition to subjects who opt to have blood collected by venipuncture, up to 25% of participants may be asked to provide blood samples by venipuncture in addition to self-collection. These subjects will be determined after the baseline specimen collection.

Self-collection of Saliva Samples (Baseline and every 2 weeks for 24 weeks)

You will collect saliva upon waking and prior to eating, drinking or brushing your teeth. Instructions for collection are provided with specimen collection kits. You will **collect and deposit** the sample **on the same day** at a designated drop-off point. The study team will provide you with your specimen collection schedule and drop-off location.

If your saliva test is positive, this may indicate active SARS-CoV-2 infection. You will be informed of this result as soon as it becomes available, advised to self-isolate and referred to a COVID Assessment Centre for a clinically approved re-test. If you are an employee at LTRI/Sinai Health or OICR, your Occupational Health & Safety personnel will also be informed.

A small number of saliva results are returned as “invalid” (failure of the assay). After one invalid result, participants will be asked to continue with their normal collection schedule. If you have two invalid assays in a row, study staff will contact you to review the collection procedure and attempt to determine if other factors (such as medications, medical conditions) could impact the saliva and thus the assay performance. Adjustments to the collection methodology may be requested, such as to collect the sample after a meal, collect saliva without a buffer (allowing the lab to try different buffers) or collect some cheek cells using a swab in an empty 50ml tube. The purpose of these adjustments is to facilitate enhanced RNA detection and therefore an assay result.

Online Questionnaires

You will complete questionnaires around the time of your blood collections (i.e. at baseline, 8, 16 and 24 weeks). These questionnaires will ask you about your exposure to COVID-19, symptoms and testing. If you miss a questionnaire, the study admin team will send an email reminder to you.

Test Results

Serology and saliva tests results will be available through an online portal and will be uploaded after each assay is completed. Participants will be provided with a personal login to access their own test results, which will be uploaded as soon as they are available.

Schedule of Study Activities

	Screen	Enrollment	**Baseline**	Wk 2 Day 14	Wk 4 Day 28	Wk 6 Day 42	**Wk 8** **Day 56**	Wk 10 Day 70	Wk 12 Day 84	Wk 14 Day 98	**Wk 16** **Day 112**	Wk 18 Day 126	Wk 20 Day 140	Wk 22 Day 154	**Wk 24** **Day 168**
E-mail invitation	X														
Review of study info (PowerPoint)	X[1]														
Server registration	X[1]	X[1]													
Eligibility	X[1]	X[1]													
e-Consent	X[1]	X[1]													
COVID questionnaires			**X**				**X**				**X**				**X**
Pick up kit		X[1]	**X**[1]				**X**				**X**				
Saliva – tube			**X**	X	X	X	**X**	X	X	X	**X**	X	X	X	**X**
Finger-prick / capillary blood			**X**				**X**				**X**				**X**
Venipuncture				X[2]			**X**[2]				**X**[2]				**X**[2]
Return assays to SHAWL drop-off box			**X**	X	X	X	**X**	X	X	X	**X**	X	X	X	**X**
Assay Results			**X**	X	X	X	**X**	X	X	X	**X**	X	X	X	**X**
X[1]	**These activities could occur on the same day or on different days**														
X[2]	**Up to 25% of participants will also provide venous blood samples. Participants may also request study blood samples be collected by venipuncture rather than self-collection if they are unable or unwilling to perform finger prick self-collection.**														

How will samples be identified?

To help protect your identity and privacy the information that will be on your blood and saliva samples will be limited to your study identification number and your coded initials (CI) (LAST letter of your first name and the LAST letter of your last name).

Can I withdraw my blood and/or saliva samples?

If you no longer want your blood samples to be used in this research, you should tell your study coordinator or Dr. Pamela Goodwin. Any unused samples will be destroyed and no further testing will be done. If tests have already been done on your samples it will not be possible to withdraw your permission for those tests.

IF YOU DEVELOP COVID-19 OR HAVE COVID-19 SYMPTOMS

If you have been diagnosed with COVID-19 or have COVID-19 symptoms (even if they are mild) that have not been investigated by a COVID Assessment Centre, go to a COVID-19 Assessment Centre. PLEASE DO NOT come to, or bring any samples to, LTRI/Sinai or OICR. If you are a LTRI/Sinai Health or OICR employee follow your Occupational Health & Safety guidelines for reporting COVID-19 symptoms and returning to work.

Please inform the study coordinator of your current status (Linda Bennett at 416-586-4800, ext. 2426 or cell: 647-885-0952 or Linda.Bennett@sinaihealth.ca).

You may be asked to collect your saliva (if it is due) and keep your specimen at home until the next collection day after your illness has resolved and, if you are an employee, Occupational Health & Safety has approved your return to work.

Risks Related to Being in the Study

This study has minimal risks. The risks we know about are described below. There is a possibility of risks that we do not know about and have not been seen in studies to date.

Blood collection may cause bleeding, bruising, discomfort, pain, scarring or rarely infections at the needle site, or dizziness. These risks are low in a healthy adult population. You may experience emotional distress if your antibody test is negative and you thought you previously had COVID-19. If this occurs you may discuss this with your primary physician and if available at your institution, employees may contact their Employee Support Program.

The saliva test is likely to generate some false negative results (25-30%) as has been found in other studies and this may be higher than in standard clinical tests. If you are informed you have a positive saliva test (i.e. are potentially actively infected) you may experience emotional distress.

The questions asked during the administration of the COVID-19 exposure or risk questionnaires may make you feel uncomfortable. You may refuse to answer specific questions or stop the completing the questionnaire at any time.

Since the data used for this study is kept on the LTRI server and only accessed by study staff via password protected computers and locked file cabinets, the risk of personal information being released inappropriately, which could lead to embarrassment or stigmatization, is extremely low.

Benefits to Being in the Study

You may receive direct benefit from being in this study by learning about your personal COVID exposure (past and present). However, your antibody test results (positive or negative) should not lead to changes in social distancing, use of personal protective equipment or adherence to Public Health recommendations. A positive saliva test, if confirmed by routine clinical testing, may allow you to take additional precautions to avoid spreading COVID-19 infection.

Information learned from this study may help other people with COVID-19 exposure or infection in the future.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study. You may leave the study at any time without affecting your employment status or academic standing at LTRI/Sinai Health/OICR or your relationship with, or care at, Sinai Health. You may refuse to answer any question you do not want to answer by clicking “I do not wish to answer”.

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

Alternatives to Being in the Study

You do not have to join this study. Your primary physician can provide advice regarding COVID-19 related concerns regardless of your participation in the study.

Confidentiality

<u>Personal Health Information</u>

If you agree to join this study, Dr. Goodwin and her study team will look at some of your personal health information (see below). At OICR, either Dr. Goodwin’s team or a designate at OICR will review this information. Personal health information is any information that could be used to identify you and includes your:

- Name;
- Employer;
- role at/relationship to LTRI/Sinai Health /OICR;
- valid email address;
- telephone number where you can be easily reached;
- date of birth;
- COVID-19 exposure and risk questionnaires;

- COVID-19 vaccination (manufacturer and dates; once the vaccine is available)
- and your COVID test results.

Only Dr. Goodwin and her clinical study staff will have access to the master list that links you to your samples. This is to allow us to contact you in the case of a positive saliva test result or to document any decision to withdraw your consent to participate.

Except as noted above, no identifiable data will be visible to other members of the team. No identifiable data will be used for analysis, communication of the study results and publication. You will not be named in any reports, publications, or presentations that may come from this study. De-identified study information may be shared with collaborating academics or with national and international regulatory agencies to help answer the study question, to get approval to sell the assay, to develop future studies on this product or for related research.

The information that is collected for the study will be kept in a locked and secure area by Dr. Goodwin for 10 years.

The following people may come to the hospital to 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 followed proper laws and guidelines:

- Representatives of the Mount Sinai Hospital and University of Toronto Research Ethics Boards.

- Representatives of Health Canada or other regulatory bodies (groups of people who oversee research studies) outside of Canada, such as the United States Food and Drug Administration.

Clinical Trial Registration

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. You can search this Web Site at any time.

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.

Expenses & Costs Associated with Participating in the Study

You will not have to pay for any of the procedures involved with this study. You will not be reimbursed for any costs associated with participation in this study. As a small token of appreciation for your participation, you will receive a $5 gift card for a coffee shop. It is possible that the research conducted using your samples and study data may eventually lead to the development of new diagnostic tests, new drugs or devices, or

other commercial products. There are no plans to provide payment to you if this happens.

Conflict of Interest

Sinai Health Foundation will pay the LTRI, Sinai Health and researchers 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.

Communication with Your Family Doctor

Your family doctor will not be informed by the study staff that you are taking part in this study. You may wish to inform your family doctor that you are participating in this study.

Questions About the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Linda Bennett at 416-586-4800, ext. 2426 or cell: 647-885-0952 or Dr. Pamela Goodwin at 416-586-8211.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office at 416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

I have reviewed the study information and this consent form. All of my questions have been answered. I know that I may leave this study at any time. I agree to take part in this study.

_____	_____	_____
Study Participant's Name/Email	Electronic Signature	Date

(You can print off a signed copy of this consent form)

The optional parts of the study:

For each optional item below, please check Yes or No. These are optional parts of the study and I understand that not participating in this portion of the study does not affect whether I can participate in the main study.

Yes	No	
		I give permission to be contacted by the study coordinator at LTRI within 1 year of study completion to request additional samples for further SARS-CoV-2 tests at LTRI or to be offered participation in future studies.
		I give permission for a portion of my de-identified sample to be shared with other University of Toronto-affiliated hospital laboratories to support their

		efforts for clinical SARS-CoV-2 testing.

Study Participant's Name/Email	Electronic Signature	Date

In-person confirmation of Informed Consent:

Study Staff name	Signature	Date