ADDENDUM - 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 Health 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. Dr. Steven Gallinger
24 Hour Phone Number	Linda Bennett (Study Co-coordinator) 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 this research sub-study because you are currently participating in the main SHAWL study. Please read this explanation about the sub-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 sub-study is voluntary and will not 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 SHAWL sub-study will involve the additional collection of finger prick blood samples onto dried blood spot (DBS) cards.

The purposes of this sub-study are to:

(i) compare results of antibody testing obtained using the regular collection tubes (the GOLD standard) to results obtained from dried blood spot samples and
(ii) (ii) collect DBS card samples that will be used as control samples in future research.

My participation will involve an extra finger prick blood collection (on the same day as one of my regular SHAWL-1 study blood collections, or the day before one of those collections).

DBS cards - I will use a blue lancet to prick my finger using the same procedure I have been using for other SHAWL-1 blood collections. Rather than collecting blood into a tube, I will place a drop of blood on each of five circles on each of three DBS cards (up to 15 blood drops).

Cryovial tube – On the same day or the next day AND after the completion of the DBS cards, I will provide my regular blood sample (using a separate finger prick and collected in the cryovial tube). If I do not have a regular SHAWL collection scheduled, I will collect the tube of blood required for this sub-study.

Instructions for collection of blood onto DBS cards will be provided in a separate document.

I understand I will receive the results of antibody testing obtained from the standard tube collection.

I understand my participation in this sub-study blood sampling protocol is entirely voluntary and I may withdraw from this sub-study (or the full SHAWL study) at any time without adversely affecting my position at Sinai Health/LTRI/OICR or my continuation in the SHAWL study. All other aspects of my Informed Consent for the SHAWL study (including confidentiality) will also apply to these additional blood samples.

I agree to participate in this additional blood sampling.

Questions

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.

You will be given a signed copy of this consent form addendum.

Printed Name of Study Participant	Signature	Date (DD/MM/YYYY)

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

Printed Name of Person Obtaining Consent	Signature	Date (DD/MM/YYYY)