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)

Before beginning this research study, you signed a Consent Form for the above referenced study. At that time, we said that we would tell you about any new information that might affect your health, welfare, or willingness to stay in the study. We recently learned of the information described below.

Based on this new information, you need to decide whether you want to continue to be in this study. Continuing to take part 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 health, academic status, employment or your care at or relationship with LTRI/Sinai Health or OICR.

Please request a copy of the original signed consent form if you need to review it. Take your time in reading this form and, if needed, reread the original signed consent form carefully. Please make sure all your questions have been answered to your satisfaction before signing this document.

New information

I have received (or will receive in the next two weeks) my first vaccination for SARS-CoV-2. I am interested in providing additional blood samples (beyond the four samples at baseline, 8, 16 and 24 weeks that are part of the SHAWL study) to allow monitoring of antibody response to my vaccination.

I agree to provide samples every 2 weeks for 8 weeks after my first vaccination [up to 4 weeks after my second vaccination if my second dose is delayed beyond 21 days if I receive(d) the Pfizer BioNTech vaccine and beyond 28 days if I receive(d) the Moderna vaccine]. I will continue to provide my usual blood and saliva samples for the SHAWL study (when the usual SHAWL blood sample falls on the same day as one of these additional post-vaccination samples, only one blood sample will be required).

I understand I will receive the results of antibody testing obtained from all blood samples I provide.

I understand my participation in this enhanced blood sampling protocol is entirely voluntary and I may withdraw from enhanced sampling (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)