MOUNT SINAI HOSPITAL
Joseph and Wolf Lebovic Health Complex

CONSENT FORM

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TITLE Incidence, clinical features, and epidemiology of infection with Influenza in health care workers and other healthy adults in Canada (Influenza Cohort Study)

SPONSOR This study has been initiated by a group of independent investigators

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You are being asked to take part in a research study. 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.

PURPOSE

The purpose of this study is to determine if health care workers are at increased risk for illness due to influenza relative to other working adults and to find out whether our current paradigm for exposure risk in acute care hospitals is accurate. It will also describe the number of cases of influenza infection, how ill people become with their illness, and whether personal factors such as age or existing chronic conditions make a person more likely to become ill with influenza.

PROCEDURES

If you wish to participate in the study, you will be asked to:

- Complete a web-based questionnaire. It will take about 10 to 15 minutes in total.
- Complete a web-based questionnaire once a week to report any symptoms of acute respiratory illness. It will take about 1-2 minutes to complete the weekly report. Weekly reporting will start November 15th and continue until mid-April.
- If you develop any symptoms of an acute respiratory illness (for instance, stuffy/runny nose, cough or fever), have a nasopharyngeal or nasal swab done, and complete an illness diary daily for as long as you have symptoms. It will take 2 to 5 minutes to complete each illness report.
- Consider having a single tube of blood taken at the beginning and end of the study. These will be used to measure your antibody level to influenza at the beginning of the study and to test whether or not you get infected with influenza even if you do *not* have symptoms.

Study Time Line

Timeline	Study requirements
Visit 1	▪ Consent ▪ Baseline questionnaire ▪ Blood sample (if you agree)
Every Monday (Nov 15 to Apr 18)	▪ Weekly diary
If you develop any symptoms of a cold or influenza	▪ Illness diary (daily) ▪ NP or nasal swab
End of study	▪ Blood sample (if you agree)

RISKS

- There may be some nasal discomfort when the nasopharyngeal and nasal swabs are taken.
- If you agree to have your blood drawn, there may be some discomfort and bruising at the site where the blood sample is taken.

BENEFITS

There are no direct benefits to you for participating in this study. It is hoped that your participation will help us assess the epidemiology of the circulating strain of influenza and help us plan for future pandemics.

CONFIDENTIALITY

If you agree to join this study, the study doctors and their team will collect some personal health information from you. Personal health information is any information that could be used to identify you and includes your name, date of birth, and answers that you complete on study forms about any medical conditions you have or medications you are taking.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 25 years. Only the study team or the people or groups listed below will be allowed to look at your records.

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 Research Ethics Board.
- 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.

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 unless required by law

If you develop influenza, the study is required to report the illness to your Medical Officer of Health (this is true of all influenza infections at all times). Staff of your public health unit may contact you to ask some questions about your illness.

Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named or otherwise identified in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used, unless you direct otherwise. No new information will be collected without your permission.

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 or your care or your employment status. You may refuse to answer any question you do not want to answer, or not answer an interview question, by saying "pass".

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

COMPENSATION
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 have to pay for any of the procedures involved with this study. You will be reimbursed for parking and travel expenses.

CONFLICT OF INTEREST
The study design, protocol, and procedures were conceived of and developed by the investigators. 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.

QUESTIONS
If you have any questions, concerns or would like to speak to the study team for any reason, please call Dr. Brenda Coleman at (416) 586-4538 or Dr. Allison McGeer at (416) 586-3118.

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, PhD, Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number 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

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 be part of the study.

In addition to the basic study that consists of completing the questionnaires and diaries, I agree to: *(please check and initial the appropriate boxes if you agree)*:

☐ _____ (initial) The study of asymptomatic infection: In choosing this option I agree to two blood samples being taken, one at the beginning of the study and the second at the end of the study.

☐ _____ (initial) Study staff contacting me by telephone or email if there are other studies of influenza for which I might be eligible. I understand that I may be asked if I am interested in participating in these studies and that I can decide at that time whether or not I wish to consider them. Whether or not I agree to consider participation in them will be completely voluntary, and will not affect my participation in this study, or any other aspect of my care.

_____	_____	_____
Print study participant's name	Signature	Date

(You will be given a signed copy of this consent form)

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

Was the participant assisted during the consent process? ? ☐ YES ☐ NO

If YES, please check the relevant box and complete the signature space below:

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

_____	_____	_____
Print Name of Translator	Signature	Date

_____	_____
Relationship to Participant	Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

_____	_____	_____
Print Name of Witness	Signature	Date

_____
Relationship to Participant