

## Seroprevalence of Influenza A (H1N1) Study

### **PURPOSE OF THE STUDY**

The purpose of this study is to describe the prevalence of 'swine' influenza infection in returned travelers to Mexico, if people can acquire the virus and remain well, and whether personal factors such as age or existing chronic conditions make a traveler more likely to become ill with this strain of influenza.

### **WHO WE NEED TO HELP WITH THE STUDY**

We need your help if you:

- 1 Are 18 years or older
- 2 Travelled to Mexico between February 1 and April 30, 2009
- 3 Stayed in Mexico for several nights (6 or more)
- 4 Whether you were healthy or became ill during or after your visit to Mexico

### **HOW THE STUDY WORKS**

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

- 1 Complete an enrolment form and a baseline personal questionnaire. It will take about 10 to 15 minutes in total; and
- 2 Have a single tube of blood taken to determine if you have developed antibodies to 'swine' influenza.

### **BENEFITS OF PARTICIPATING IN THE STUDY**

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

### **RISKS OF PARTICIPATING**

If you agree to have your blood drawn, there may be some discomfort and bruising at the site where the blood sample is taken.

### **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, addresses, 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 study organizing committee,
- Representatives of the Research Ethics Board(s).

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 have evidence of antibodies in your blood to 'swine' influenza, we will share this information with the Medical Officer of Health. Staff of your public health unit may contact you to ask some questions about whether or not you were ill during or after travel, and if anyone you

know is or has been ill.

With the exception of mandatory reporting to the Medical Officer of Health, no information about you that is sent out of the hospital will contain your name or address, or any information that may identify 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 care and/or 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.

You will not have to pay for any of the procedures involved with this study.

You will not be reimbursed for transportation, meals, or time associated with participation in this study.

### **STUDY FUNDING**

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

### **QUESTIONS**

If you have any questions or are interested in enrolling in this study, please: call the

Infectious Disease (ID) Research office

**416-586-4800 ext. 4161**

or email us at

[IDresearch@mtsinai.on.ca](mailto:IDresearch@mtsinai.on.ca)

### **PRINCIPAL INVESTIGATORS**

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