Toronto Invasive Bacterial Diseases Network

PARTICIPATE IN A RESEARCH STUDY

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Scarborough Health Network
Sunnybrook Health Sciences Centre
Trillium Health Partners
University Health Network

Study Title: **PR**oposal to assess s**E**rum neutralization against **ci**rculating A(H3N2) strains in the 2025-2026 **SE**ason (PRECISE-Immunogenicity)

Study Doctors: Dr. Christopher Kandel, Sinai Health System
Dr. Allison McGeer, Sinai Health System
Dr. Christina Guzzo, University of Toronto

Study sponsor: Sinai Health System
Study funder: PRECISE, Government of Canada

Introduction:
You are being asked to take part in a research study. Please read the information about the study as presented in this form. The form includes details on the study's risks and benefits that you should know 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 better understand how well antibodies in blood from people who have received influenza vaccines are able to bind and kill the new strain of influenza virus (called subclade K). We will be comparing the ability of serum from people who have had different vaccines to bind to and kill subclade K of influenza A(H3N2).

Who can participate in this study:
To participate in this study, you must not have an illness that affects your immune system, and you must not have had an laboratory-confirmed influenza infection in the last six months. You must have received a dose of influenza vaccine since September of 2025, and it must have been either high dose vaccine (one of the vaccines for those over 65 years of age), or standard dose, unadjuvanted vaccine (one of the vaccines recommended for healthy adults under 65 year of age). You will need to bring proof of vaccination that has the date of your vaccination, and if you are 65 years of age or over, the type of vaccine you got, with you to your study visit.

Study Procedures:
If you agree to participate in this study, you will be asked to:

- Answer a brief questionnaire about your health and your receipt of influenza vaccines in 2024 and 2025
- Provide proof of vaccination against influenza this fall which specifies which vaccine your received and when
- Have a blood sample drawn (4 teaspoons or 20mls)
- Agree to your blood samples being shared with researchers studying influenza viruses and the body's response to them as part of this study

CONSENT FORM TO

You will also be asked to consider some optional parts of the study:

- Agreeing to your samples being stored and shared for new studies after this study is over
- Allowing study staff to contact you after this study is over to ask if you would be willing to consider being part of other studies
- If you develop an acute respiratory infection between now and April of 2026, reporting this to the study, and submitting a nasopharyngeal or mid-turbinate swab (you may do this yourself, or have study staff collect it), for testing for influenza. If you test positive for influenza, you will be asked to agree to have a blood sample (4 teaspoons/20 mls) drawn 3-7 weeks after the onset of infection.

You can agree to help with all or only some of these things at the end of this form.

Risks and Benefits: Having your blood drawn is painful and may be associated with some bleeding and bruising at the site your blood sample is taken, and having an NP swab is uncomfortable. There are no other physical risks to taking part in this study and no risk to having the samples stored in the research lab. These samples will be stored with a code only so that you cannot be identified. You will receive no direct benefit from being in this study. You will receive a $25 gift card as partial reimbursement for time, travel and parking costs for the first study blood sample. You will receive 2 $25 gift cards if you visit the hospital to submit an NP swab when you are ill, or if you visit the hospital to submit a convalescent blood sample after an influenza infection. We hope that the results may help other patients in the future. It is possible that the use of your samples may lead to new diagnostic tests, vaccines or treatments for new types of influenza. There are no plans to provide payment to you if this happens.

Confidentiality: 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 except as required by law. You will be identified with a study number only, which will be used on all study documents and laboratory samples. Identifying information collected for the purpose of contacting you will be kept separate from your study files and will be destroyed once the data collection and analysis are finished. No names or identifying information will be used in any publication or presentations and no human genetic information will be used or collected.

Because we are studying an infection with a new strain of Influenza, many researchers will be working on better understanding this infection, and on developing tests to diagnose this infection, study vaccines, and treatments. Having enough different samples is important for these studies. For these reasons, we are asking for permission to share your study samples and information about your illness with other researchers at universities, companies, and public health laboratories. A group of study doctors and the Research Ethics Board at Sinai Health System will make sure that these requests are only used in research related to respiratory infections. If parts of your samples, and/or your data are shared, they will be de-identified; that is, it will not be possible for researchers outside this study to find out who you are, or to link your sample or data to you. If the information is transferred outside of Canada, it will be subject to the laws of that country where it is stored, which may not be as strict as Canadian laws. However, only de-identified data and samples will be transferred. Samples may be stored for up to 20 years. When you give consent to the study, we will ask you specifically whether you agree to this use of your samples.

Representatives of the hospital including the Research Ethics Board may look at the study records and at your personal health information related to this study only to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines.

If at any time you decide that you no longer want your samples to be used in this added research, you should tell the study coordinator (contact information below), who will ensure that the leftover part of the samples are destroyed. If tests have already been done on your samples, it will not be possible to withdraw those results. However, no further testing will be done.

Voluntary Participation: Your participation in this study is voluntary. Whether or not you agree to participate will not affect your care at the hospital in any way. 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. During the study interview, you may refuse to answer any question you do not want to answer by saying "pass". If you leave the study, the information that was collected before you left the study will still be used to help answer the research question, unless you tell us to remove it. No new information will be collected.

Your legal rights: 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. 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.

Questions about the Study:
If you have any questions, concerns or would like to speak to the study team for any reason, please call Dr. Allison McGeer or Dr. Christopher Kandel, the primary investigators, or the research coordinator, at 416-586-4600 ext. 2761. This study has been reviewed by the Sinai Health System Research Ethics Board (REB). The REB is independent of the researchers. If you have any concerns or questions about your rights or your experiences as a research participant, you may contact the REB at 416-586-4875, during business hours. The research ethics board is a group of people who oversee the ethical conduct of research studies. The research ethics board is 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 the use of my information as described in this form.

I confirm that to the best of my knowledge my immune system is not compromised, and that I have received an influenza vaccine this fall which was unadjuvanted.

I consent to answering some questions about my health and recent vaccines I have had, and to having a blood sample drawn now for the study and shared for use by researchers studying influenza viruses and the body's response to them as part of this study.

The following parts of the study are optional. Please circle YES or NO and add your initials for each optional part

	circle & initial boxes:	
1. Reporting acute respiratory illness to the study, having an NP or mid-turbinate swab to find out if I have influenza, and, if I have influenza, having a blood sample (4 teaspoons) taken after I recover I consent to contacting the study coordinator if I develop an acute respiratory illness (the person taking your blood will let you know how), having an nasopharyngeal or mid-turbinate swab collected for influenza testing, and submitting a blood sample 3-7 weeks after my illness began if I have influenza.	**YES**	**NO**
2. Storage and research use of my test samples, blood and information I consent to the storage of my leftover blood for up to 20 years. I understand that these samples, and, if it is needed, de-identified information about me may be sent to other research laboratories in and outside of Canada. These samples will only be used for the purpose of developing vaccines, tests, or treatments for influenza and other respiratory infections. No human genetic testing will be performed on these samples.	**YES**	**NO**
3. Permission to contact me about future research I agree that the study can contact me about participating in future research about respiratory infections	**YES**	**NO**

Print Study Participant's Name _____ Signature _____ Date _____

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 _____

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For participants who have agreed to contact about future studies:

Primary telephone number: _____

Secondary telephone number: _____

Email address: _____
Please note, if you provide your email address, that communication via email is not absolutely secure. If we contact you by email, it will be only to ask if you could call us or provide a contact number for a discussion about a study. We do not recommend that you communicate sensitive personal information via e-mail.

Mailing address: _____

Alternative person to contact if none of the above

Name: _____

Telephone number: _____
(This should be a person the study may call; you should let them know that if study staff cannot contact you, they will call this person, identify that they are from a study and ask them to get in touch with you to ask if you would contact the study staff. No information about the study or you will be shared)