Québec study on the incidence of CMV infection infection among early childhood educators, and development of strategies to prevent infection

INFORMATION AND CONSENT FORM
*** CONTROLS: HÉMA-QUÉBEC PLASMA DONORS *

APPROUVÉ PAR LE COMITÉ D'ÉTHIQUE
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CHU SAINTE-JUSTINE

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HÉMA-QUÉBEC and the *Centre hospitalier universitaire Sainte-Justine* (CHUSJ) are asking you to take part in a research project in collaboration with the pharmaceutical company Moderna, because you are a plasma donor between the ages of 18 and 45 who is not professionally in contact with children under 36 months of age.

This consent form is part of the standard procedure for ensuring free and informed consent to participate in a research project. The information contained in this form will give you a general idea of the research project and what your participation entails. If, at any time, you would like to know more about the following, do not hesitate to ask us. Please take the time to read and understand these explanations, and do not hesitate to ask the research team any questions you may have.

A. Introduction

Cytomegalovirus (CMV) is a common virus found in around 50% of Canadian adults, causing lifelong infection. It is possible for individuals to be infected with several different strains of CMV. This infection generally causes no health problems in healthy adults. However, if infected during pregnancy, CMV can be transmitted to the baby, causing potentially serious complications.

The goal of this study is to determine the frequency of CMV infection in women who, like you, are not professionally directly exposed to CMV via very young children, and to compare this frequency with that of early childhood educators in Quebec, to develop strategies for preventing the virus in this population.

B. What does this study involve, if you agree to participate?

Your participation in the study is expected to last approximately one year and includes the following:

1) Shortly after consenting to participate in the study, a member of the HÉMA-QUÉBEC team will contact you to schedule a plasma donation appointment on two occasions: once at the beginning of the study and a second time 12-15 months later.
2) At each of these 2 appointments, Héma-Québec staff will collect your plasma as usual. During each appointment, the nurse will draw 3ml of plasma directly from the bag of plasma that has just been collected. You will not undergo any additional sampling, and the same total amount of plasma as previous visits will be collected from you. The sample will be coded and sent to Héma-Québec's Research & Development department. Héma-Québec will then send your plasma samples to the CHUSJ to be tested for CMV, following the usual procedure of tests for blood-borne diseases.
3) Following the collection of each of these samples for the study, on the same day or within 7 days, you will receive an e-mail directing you to the online questionnaire (via a platform called REDCap). You will therefore need a valid e-mail address to participate in the study. You will also need to read and respond to any study-related e-mails you receive. The first questionnaire (V0) and the final one (V12) should each take about 15 minutes to complete. The first questionnaire will include questions of a personal nature, as well as questions about your job and your level of exposure to the CMV virus, both at home and at work. Some questions may be very personal, and you may choose not to answer them. The end-of-study questionnaire will include questions related to your level of CMV exposure at work and your knowledge of the virus.
4) If you donate plasma to Héma-Québec several times a year, only 2 samples of 3ml will be taken for the study: once at the beginning of the study and a second time, 12-15 months later.

C. During the study, if one of my plasma samples turns out to be positive for CMV, will I be informed?

The laboratory responsible for the study at CHUSJ will test all control plasma samples for CMV, including yours. As these tests will be performed several months after your donation, the results will no longer be clinically significant for you. Consequently, the results will not be sent to you.

D. What laboratory tests will be performed on my samples?

Study samples will be analyzed to test for the presence of CMV and your immune response to this virus. This may include tests for antibodies (a protein in the blood, produced in response to a foreign substance or infection), tests for the presence of the virus and tests for viral genetic material. These results will not be sent to you.

E. What will happen to the remains of my plasma samples once the analysis is complete?

We ask for permission to keep your leftover plasma in a biobank (along with your data) once the study analyses have been completed. Your leftover samples will be kept for as long as the researchers responsible can ensure their quality. However, the biobank storage is optional: you can agree to participate in the study and refuse to have the remains of your plasma samples stored in the biobank. Your decision whether to participate in the biobank is documented on the last page of this document.

If you agree to have the remains of your plasma samples stored in the biobank, your samples will be coded and stored in the laboratories of Dr. Boucoiran and Dr. Gantt at CHUSJ for use with your data in future studies on CMV and/or respiratory infections, including related pathologies and treatments. Data and/or samples may be shared with researchers at CHUSJ or elsewhere. Any future project **must first** be approved by a qualified research ethics committee and then authorized by the biobank's access committee, which includes a Héma-Québec representative. Neither your data nor your samples will belong to Moderna Pharmaceuticals. However, should Moderna Pharmaceuticals wish to access your data or samples for a future research project, this proposed project will be subject to the same regulations as any other project, including approval by a qualified research ethics committee and the biobank's access committee.

If you refuse to have the remains of your plasma samples stored in the biobank, your plasma samples will only be used for the present study and will be destroyed afterwards.

If you decide to withdraw your samples from the biobank, you will be asked whether you wish your data and/or biological material already collected to be destroyed. If so, these data and/or biological samples will be removed from the biobank.

F. What will happen to my *data* once the study is over?

Once this study has been completed, we ask for your permission to store your coded data in a database for use in future studies on CMV or respiratory infections, which would need to be approved by the CHUSJ Research Ethics Committee. This component of the study, the storage of your data, is optional - you can agree to participate in the study and refuse to have your data stored in the database. Your data will not belong to Moderna Pharmaceuticals. However, should Moderna Pharmaceuticals wish to access your data for a future research project, this proposed project will be subject to the same regulations as any other project, including approval by a qualified research ethics committee and the biobank's access committee.

If you do not wish your data to be stored in the database, it will only be used for the present study and will be destroyed afterwards.

G. What are the benefits of the study?

The information obtained from this study will contribute to new knowledge about the frequency of CMV infection among childcare workers and will help determine how best to prevent infection in childcare settings. There are no direct benefits for you to participate in this study. However, the knowledge gained could, in the future, help women working in daycare.

H. What are the risks and inconveniences of the study?

There is no risk or inconvenience to you in recovering your sample and using it in the study.

I. Costs and financial compensation

Financial compensation will be offered to you twice in the form of gift cards: a first financial compensation in the amount of $50 after completing the online questionnaire following the first plasma donation, and another $50 after completing the online questionnaire following the second plasma donation at the end of the study.

Please note that Dr. Boucoiran and others involved in the study will not receive any money for your participation.

J. Confidentiality

To determine your eligibility for the study, Héma-Québec has communicated your personal information (first name, last name, gender, age, ethnic origin and contact information) to the CHUSJ. This communication was made in compliance with the applicable law on the protection of personal information.

During your participation in this study, Héma-Québec and the CHUSJ will collect and record personal information about you in a research file, which will be kept under lock and key. Your information will be collected during an interview with a Héma-Québec representative and/or a CHUSJ representative, as well as via online questionnaires (REDCap). All information gathered and used during this study will remain confidential unless otherwise provided by law. Your identity will be protected by replacing your name with a research number on plasma samples, questionnaires and study data. This code will be kept under lock and key by Dr Boucoiran, who oversees the project at CHUSJ, and only the research team will have access to the code linking your name to this number. Your personal data will only be consulted by the research team insofar as consultation is necessary to achieve the objectives of the study.

Personal information will be retained for as long as necessary to meet the scientific objectives of the study.

If information from this study is published or presented at scientific meetings, your name and other personally identifiable information will not be used or published.

Héma-Québec and CHUSJ may use your personal information to contact you. Personal information collected during the study will NOT become part of your medical record.

To ensure your protection and the quality control of the study, your research file may be consulted by a person mandated by Héma-Québec's Research Ethics Committee and/or that of the CHUSJ and/or by the following organizations:

- The sponsor(s) of this project,
- Government regulatory agencies,
- The research ethics committees of the Quebec hospitals participating in the study.

These organizations all adhere to a confidentiality policy, and their employees and members, in the case of research ethics boards, are bound by confidentiality commitments.

You have the right to access your personal information, to have it corrected if necessary, and to restrict or refuse access to certain persons or categories of persons. To exercise your rights or to obtain more information, please contact the person in charge of access to documents and protection of personal information at Héma-Québec at responsable.acces@hema-quebec.qc.ca or contact Suzanne Taillefer (Provincial Study Coordinator) at suzanne.taillefer.hsj@ssss.gouv.qc.ca .

You may withdraw your consent for the use and disclosure of your personal information, in which case it will no longer be used or disclosed, if applicable. However, if your blood sample has already been analyzed, you will no longer be able to withdraw your consent for the use and disclosure of your personal information associated with that sample, to ensure the integrity of the study and support the conclusions reached.

K. Data Identification

Study data are always coded numerically to prevent identification of participants. You will be assigned a research code to identify your clinical data and biological samples. The assigned research code will be the only information used to identify the various data obtained during this study. This code will be kept under lock and key by Dr. Boucoiran, who oversees the project at CHUSJ, and who will be responsible for the safekeeping of all research data throughout the study. It is possible that a delegate of the research ethics committee may have access to the research data to verify the sound management of the study.

L. Storage location and retention period for data and biological samples

Clinical data, including personal information communicated by Héma-Québec to the CHUSJ for study purposes, is stored electronically on CHUSJ servers, in an electronic database that meets all CHUSJ security criteria. The electronic platform used for data collection will be accessible only to you and members of the research team.

Certain personal data of an administrative nature, including those related to financial compensation, will be kept in paper form, under lock and key, in the offices of the research team under the direction of Dr. Boucoiran, at the CHUSJ, and/or in electronic form in a secure file on a CHUSJ server.

Coded biological samples will be stored in the laboratories of Dr Boucoiran and Dr Gantt at the CHUSJ.

Clinical data and biological samples will be kept for as long as Dr. Boucoiran can ensure their physical integrity.

Again, if you refuse to allow your data and samples to be stored in the database, they will only be used for the purposes of this study and will subsequently be destroyed.

M. Freedom of Participation

Your participation in this study is **voluntary**. You may choose not to participate, and you may withdraw from the study at any time, without giving any reason.

If you choose to **participate** in this study,

a) You are free to refuse to answer certain questions related to the study.

b) If you so request, your biological specimens and data may be destroyed if they have not already been analyzed and/or published.

c) The data and results of biological specimens already analyzed will be kept, to ensure the quality of the research.

N. Contacts

If you have any further questions about this research project, please do not hesitate to contact us.

At the CHUSJ :

You can reach **Dr Boucoiran** by telephone: **(514) 345-4931 ext: 7169**, one of the research nurses: **(514) 345-4836**, or the provincial study coordinator **Suzanne Taillefer** by email: suzanne.taillefer.hsj@ssss.gouv.qc.ca

For information on your rights as a participant in this research project, please contact the Local Service Quality and Complaints Commissioner: **(514) 345-4749**

At Héma-Québec:

You can call the nurse in charge of samples at Medical Affairs and Innovation: **(418) 780-4362 (ext. 3256)** or at **1-800-267-9711 (ext. 3256)**.

After normal business hours, you can reach Donor Customer Service at **1 800-847-2525** and leave a message clearly indicating the title of the study you are taking part in and your contact details. Your message will then be forwarded to the people in charge of the study.

If you have any further questions about your rights as a participant in this research project, or if you have a complaint, you can contact the Ethics Committee secretary at **(514) 832-5000 (ext. 5370)** or **toll-free** at**: 1-888-666-4362 (ext. 5370)**.

CONSENT

*** CONTROL: PLASMA DONOR - HÉMA-QUÉBEC ***

By signing this consent form, I certify that

- I clearly understand the information regarding this consent and agree to participate in this study. All my questions have been answered to my satisfaction.
- I am familiar with the risks and inconveniences of plasma collection.
- I understand that I am completely free to participate in this study.
- By agreeing to participate in this study, I do not waive any of my rights, nor do I release the physician in charge of the research project, the sponsor and the institution from their civil and professional responsibilities.

I also accept :

- To provide the research team with a valid e-mail address and cell phone number that will allow me to use REDCap and thus participate fully in the study, knowing that all information I provide will remain confidential.
- That my personal information be collected, used and disclosed for the purposes set out in this consent form.

Optional aspects of the study:

1a. I accept that the remains of my **plasma samples** (<u>including my data</u>) be banked for use in future studies on CMV and/or respiratory diseases. I understand that these studies must first be approved by a qualified ethics committee.

☐ Yes, I accept ☐ No, I refuse → IF NO:

1b. I accept that **only** my **data** (and <u>not</u> my biological samples) be stored for use in future studies on CMV and/or respiratory diseases. I understand that these studies must first be approved by a qualified ethics committee.

☐ Yes, I accept ☐ No, I refuse

2. I accept that, **in the future**, the CHUSJ research team **may contact me** to invite me to participate in other research projects for which I may accept or refuse to participate.

☐ Yes, I accept ☐ No, I refuse

Name of Héma-Québec donor (Please print) **Signature** **Date**

Email for the study **Telephone**

I explained all relevant aspects of the study to the participant and answered all questions she asked. I informed her that participation in the study is free and voluntary, and that participation can be discontinued at any time.

Name of person who obtained consent (Please print) **Signature** **Date**