CMV DETAIL (Improving iDEntification of maTernAl CMV reInfection and characterization of congenitaL CMV strains)

~ Participant Information and Consent Form ~

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Non-Emergency Contact: Dr Elisabeth McClymont, 604-833-1838

INTRODUCTION

Throughout this consent form, when we say “you” or “your”, we mean you or your child.

You are being invited to participate in CMV DETAIL because your infant received a positive diagnosis of congenital cytomegalovirus (CMV) infection. The study team, listed above, is trying to better understand the importance of maternal reinfection for congenital CMV (cCMV). We are trying to better understand how often mothers are infected with a new type of CMV during pregnancy, and which types result in their infant being infected with CMV. This is important as it will help inform prevention methods and determine which types of CMV should be considered for the development of vaccines in the future. This consent form will provide you with information on the purpose of the study, how it may help you, any risks to you, and what is expected of you during the study. Once you understand the study and if you agree to take part, you will be asked to sign this consent form. You will be sent a copy of this form to keep for your records. This project is funded by the National CMV Foundation.

PURPOSE

Cytomegalovirus (CMV) is the most common congenital infection (i.e. infection of an infant happening during pregnancy or delivery) globally, resulting in an enormous burden of childhood hearing loss and neurodevelopmental delay. The aim of CMV DETAIL is to better understand how often a mother/parent is infected with a new type of CMV during pregnancy, and which types result in their infant being infected with CMV. This research project will use the information we gather to better understand congenital CMV infection and help guide the development of an effective vaccine against CMV.

STUDY ELIGIBILITY/SCREENING

In order to be eligible to participate, you must:

1. Have delivered, or be delivering, an infant with a presumed or a confirmed diagnosis of congenital CMV infection
2. Have delivered, or be delivering, in British Columbia
3. Your pregnancy will conclude or has concluded in or after 2018.

SAMPLE COLLECTION

If you decide to take part in this study, and you sign this consent form, you may consent to the use of your leftover samples and/or the use of your infant's leftover samples. You do not have to agree to the use of every sample. We will use samples that were already collected during your regular clinical care; no additional samples will be collected.

SCHEDULE OF STUDY TIMEPOINTS

TIME POINT 1: First trimester

As a part of your regular clinical care, a blood sample was collected from you at an early prenatal visit. This sample is currently stored at the BC Centre for Disease Control. No additional samples will be needed for the study.

TIME POINT 2: Delivery

As a part of your regular clinical care, samples were collected from you and your infant, such as maternal blood, infant blood, infant urine, and/or infant saliva. These samples are currently stored at the BC Centre for Disease Control and BC Children's Hospital. No additional samples will be needed for the study.

SAMPLE TESTING

All samples listed above will have identifying information removed and then will be sent to the Gantt/Boucoiran Lab at CHU Sainte Justine in Montreal for study tests. Any leftover samples after testing will be destroyed at the end of the study. The custodians of these samples are Dr. Inna Sekirov (UBC), Dr. David Goldfarb (UBC), Dr. Soren Gantt (U. Montreal), and Dr. Isabelle Boucoiran (U. Montreal). All samples are identified with your study ID only, no personal identifying information will be listed.

CMV ELISA and CMV-Scan assays will be performed on maternal early pregnancy and delivery blood samples in order to determine the nature of antibodies to CMV and presence of the CMV virus. Next-generation sequencing and CMV genomic analyses will also be performed on infant specimens using methods to determine the type of CMV virus. Your samples collected for this study may be tested with new laboratory tests if they become available.

Health information will be extracted from your and your baby's clinical record if available. Information to be extracted will include the reason for CMV testing, details about your pregnancy and delivery such as gestational age at sample collection and age of your child at sample collection, and details about your infant's health such as the results of their first hearing test.

RISKS AND/OR DISCOMFORTS

The risk for you that exists is accidental release of information. As our research team is highly experienced with research and with the safeguards afforded by using a secure database within the Women's Health Research Institute, this risk is felt to be extremely small.

BENEFITS

You will not receive any direct benefit from participating in the study. However, knowledge gained from this study may benefit pregnant women/people and their infants in the future.

NEW FINDINGS

You will be told of any new information learned during the course of the study that might cause you to change your mind about staying in the study.

VOLUNTARY PARTICIPATION

Your participation in this research study is entirely voluntary. You are under no obligation to be included in this study and you may withdraw from this study at any time without providing reasons. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected. You have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn, for example, where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. Similarly, if a specimen has already been used, we can only delete data obtained from it. If you would like to request the withdrawal of your data, please contact the study investigator or research manager.

IN CASE OF RESEARCH RELATED INJURIES

Signing this consent form in no way limits your legal rights against the investigators, or anyone else, and you do not release the study doctors or participating institutions from their legal and professional responsibilities.

CONFIDENTIALITY

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of UBC Children's and Women's Clinical Research Ethics Board, and any other entity as required by law for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

Findings from this study will be shared with our partners and collaborators. These findings will not contain any information that identifies you, such as your name or date of birth. These data will also be published and/or presented at scientific meetings.

HEALTH INFORMATION AND SECURITY

As part of this study, we plan to access antenatal and infant samples already collected from your regular clinical care. Samples collected during pregnancy are routinely stored at the BCCDC for up to one year. In order to link you to your samples stored at the BCCDC we will use your first name, last name, birth date, and provincial health number (PHN) stored in the secure study database. Linkage will be done by only one authorized member of the study team, within a high-security environment. The study team follows strict provincial privacy policies.

DISCLOSURE OF RACE/ETHNICITY

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence the generalizability of the findings. You should be aware that providing this information is not mandatory.

AFTER THE STUDY IS FINISHED

Please contact Dr. Elisabeth McClymont at elisabeth.mcclymont@cw.bc.ca with any requests you may have about study updates or results. We will not be providing individual results from this study. Once overall results have been published, Dr. McClymont or a member of the UBC RID research team will disseminate a copy of the journal article with a summary to all participants.

ADDITIONAL INFORMATION

If you have any questions or desire further information about this study before or during participation, you can contact Dr. Deborah Money, the study investigator at 604-875-2194 or Dr. Elisabeth McClymont, postdoctoral fellow at 604-833-1838 or elisabeth.mcclymont@cw.bc.ca.

If you have any concerns or complaints about your rights as a research participant, your experiences while participating in this study, or your privacy, please contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number (H21-02213) when contacting the Complaint Line so the staff can better assist you.

FUTURE RESEARCH

We understand that some women are interested in women's health issues and women's health research. Creation of a database of women who are interested in being involved in future research will allow us to inform them about upcoming studies for which they may be eligible.

The research team would like to ask you for permission to contact you in the future for opportunities related to this current project, and other research opportunities. If you agree to have your contact information kept on file, it does not mean you are obligated in any way to participate in any future research.

☐ I AGREE that a member of Dr. Money's research team may contact me in the future for follow-up or further related research related to this study.

☐ I AGREE that a member of Dr. Money's research team may contact me in the future to ask if I am interested in participating in other research studies not described in this form.

Phone: _____

Email: _____

Mailing address: _____

Other: _____

☐ I DO NOT AGREE to have my contact information kept on file or to be contacted for future research.

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CMV DETAIL Participant Consent and Signature Page

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my and my child's participation in this study is voluntary.
- I understand that myself or my child are completely free at any time to decline to participate or to withdraw from this study at any time, and that this will not change the quality of care that myself or my child receive.
- I authorize access to my and my child's health records and samples as described in this consent form.
- I understand that I am not waiving any of my or my child's legal rights as a result of signing this consent form.
- I understand that this study will provide no direct benefit to me or my child.

I will receive a signed copy of this consent form for my own records

I have read this form and I consent to my and my child's participation in this study

_____

Printed name and signature of participant Date

_____

Printed name, signature and role of person obtaining consent Date

The consent was done in the following language: _____

If the consenting process was not done in English, the person signing below acted as an interpreter/translator for the participant:

_____

Printed name and signature of interpreter/translator Date