

HREC Project Number: HREC/18/RCHM/273

Research Project Title: Hearing Screening for congenital CytoMegalovirus (HearS-cCMV Project)

Coordinating Principal Researcher: Dr Valerie Sung, MBBS FRACP MPH PhD

Principle investigator: Dr Rosalynn Pszczola, MBBS

Version Number: 6 **Version Date:** 01/04/2019

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to invite you and your baby to participate in a research project that is explained below.

This document is 8 pages long. Please make sure you have all the pages.

What is an Information Statement and Consent Form?

An Information and Consent Form tells you about the research project. It clearly explains exactly what the research project will involve. This information is to help you decide whether or not you would like your child to take part in the research. Please read it carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Taking part in the research is up to you

It is your choice whether or not your child can take part in the research. You do not have to agree if you do not want to. If you decide you do not want your child to take part, it will not affect the care your child gets.

Signing the form

If you want your child to take part in the research, please sign the consent form at the end of this document. By signing the form, you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project.

We will give you a copy of this form to keep.

HearS-cCMV Master Participant Information Sheet/Consent Form v6 01/04/2019

Sunshine Hospital, Western Health, Site Master Participant Information Sheet/Consent Form v6 01/04/2019

Working in Partnership with



1. What is the HearS-cCMV project about?

The HearS-cCMV project team is working with the Victorian Infant Hearing Screening Program (VIHSP) to provide an additional service that doctors are recommending to Victorian families. This project involves an extra test for babies who do not pass their second hearing screen who are born at selected Victorian hospitals. This extra test uses a sample of the babies' mouth saliva (spit) to see if there was a virus (germ) called cytomegalovirus (CMV) present at the time of their birth. If the virus is present from birth it is called congenital CMV. For a very small number of babies, congenital CMV can be the cause of life-long hearing loss. For some of these babies, there may be a treatment available if the doctors know this virus is present early enough. Therefore, it is very important to know as soon as possible if this virus is there. At the moment, this saliva test is not routinely offered early enough for an accurate diagnosis to be made. This project ensures your baby is given a chance to receive this simple test, and will help to gather information about how this can best be done. This will help us work out the best way of offering CMV testing across the whole state to babies who do not pass their second hearing screening.

CMV is a very common virus and it is estimated that more than 60% of Australian adults have had this virus at some time. It is spread by direct contact (e.g. through handling objects with saliva on them then touching the eyes, nose or mouth without first washing your hands). If you have had CMV, it is possible that you did not know as you may have only experienced flu like symptoms or no symptoms at all. At the moment, there is no vaccination available to prevent the spread of CMV from person to person. If a pregnant mother is infected with CMV during pregnancy, there is a chance that her baby can also be infected with CMV. Research suggests that approximately 1.7% of babies are born with the CMV virus. Babies born with congenital CMV may or may not experience medical problems. Some babies with congenital CMV can be born with a hearing loss, or develop hearing loss over time. Congenital CMV accounts for around 15-20% of congenital hearing loss that affects both ears. For some babies with congenital CMV, hearing loss and other medical problems, giving them a treatment within the first month of life may be beneficial. We do not yet know whether the treatment benefits babies with congenital CMV and/or hearing loss without other medical problems. HearS-cCMV is a first step in helping us answer this important question, and also gives families an option to consider a treatment that is only available in the first month of life.

If the saliva test proves your baby has the CMV virus, we will help you book an appointment with a specialist who will discuss the management options with you.

The earlier the saliva swab is taken and tested, the sooner the treatment can be offered if it is medically appropriate.

2. Who is funding this research project?

This project is funded by the University of Melbourne, the Deafness Foundation, The Mercy Hospital for Women and the Monash Children's Hospital.

3. Why is my child being asked to take part?

We think that your baby meets the HearS-cCMV entry requirements. Your baby can be part of HearS-cCMV if he/she:

- Is aged 21 days or less
- Did not get a 'pass' result on their second VIHSP hearing screen, i.e. received a 'refer' result

- Had their VIHSP hearing screen done at the Royal Women's Hospital, Mercy Hospital for Women, Monash Children's Hospital or Sunshine Hospital.

We know that your child still needs further hearing testing to confirm whether he/she has adequate hearing for speech and language development. The hearing tests are often done after 21 days, when taking a saliva sample for CMV is no longer accurate. Therefore, we are testing children who are at risk of hearing loss as they have not passed the second VIHSP hearing screening.

4. What do we need to do in this research project?

If you would like to take part in this project, you must:

- Read the information in this pack. If you have any questions you can speak to your VIHSP Area Manager or the HearS-cCMV project team. The project team contact details are listed at the end of this form.
- Sign both consent forms. Don't forget to complete the details at the bottom about your child and their last feed. If you can, take a photo and either text or email it to the study team (see page 5 for contact details). Keep one copy and return the other in the white envelope.
- Next, take out the saliva collection kit and double check that your child's name and date of birth are spelt correctly on the pathology slip AND on the saliva tube. If not, please fill these details in using a black or blue pen.
- Collect a saliva sample from your child using the kit provided (see instructions below).

The timing of the saliva sample is very important. It needs to be taken before your baby is 21 days old.

Two important things to note before taking the saliva sample are:

1. If you are breastfeeding or giving your baby expressed breast milk don't take the sample for at least 1 hour after the feed. If your baby is having formula you can complete the saliva sample at any time.
2. Take the sample as soon as possible, preferably before your baby turns 21 days old.

How to take the saliva sample: (A link to a video on how to take the swab can also be found at

<https://www.mcri.edu.au/research/projects/hears-ccmv-project>)

- Put on the gloves and twist the top of the swab stick and pull it out.
- While holding onto the top of the swab stick, place the swab into your baby's mouth
- Hold the swab against your baby's cheek for about 1 minute to soak up the saliva.
- Put the swab back inside the tube and push it tightly closed to make sure it is sealed.
- Fill in the details at the bottom of the pathology slip. These include the date & time the saliva was collected.
- Place the swab tube and the pathology slip in the plastic bag and put the plastic bag in the express post mail bag and seal it.
- As soon as you can, return the yellow express post mail bag and the white reply-paid envelope to the research team. If you are still in hospital, give both envelopes to the nurse or midwife or a hearing screening staff. If you have left the hospital, please post them back as soon as you can at

Australia Post. Or you can put the yellow express post envelope into a yellow express post mail box and the white reply-paid envelope into the ordinary red mail box.

Once your child's saliva sample is received, it will be tested for the CMV virus at the Royal Children's Hospital. It usually takes 1-2 days for the results to become available.

- If your child does not have this virus, we will not contact you. If you do not hear from us and would like further information about your child's test results, please contact us.
- If your child has the CMV virus, a doctor who is part of the HearS-cCMV team will contact you to arrange a face to face medical appointment for your child to discuss these results. The study team will also organize for your child to have a blood test, a urine test, an eye examination and an ultrasound of the head. These tests help the specialist decide on the best management for your child, and you will be provided with all the results from these tests at the appointment.
- If your child has the CMV virus and is also found to have any hearing loss the HearS-cCMV team will also organize an MRI (Magnetic Resonance Imaging) of the brain/ears. This may help with your child's care in the future

There is no cost to your family to take part in this project, it is free.

You can also help the project by giving us permission to:

- share your data anonymously with other research groups hoping to answer similar questions about the causes and treatment of hearing loss or congenital CMV. If you agree, researchers will only have access to your project ID number but not your name or other personal details.
- store your child's saliva sample for use in future ethically-approved research projects. These may help answer future questions or do tests that don't exist yet to further explore the causes and treatment of hearing loss or congenital CMV.
- contact you again about future research projects that help children with congenital CMV and/or hearing loss.

Being able to share information will help answer questions that need bigger groups of children, without having to set up new studies that can take a lot of time and money to complete. There are strict ethical guidelines for sharing and using research information. Any future use of information collected in this research project will be shared in such a way that you or your child cannot be identified.

You can indicate if you are willing to consent to these extra things by ticking the appropriate box on the consent form at the end of this document.

3. Can my child stop taking part in the project?

Your child can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If your child leaves the project we will use any information already collected unless you tell us not to. If you have already returned your child's completed saliva swab, we will perform the CMV test on the swab and we are medically obliged to inform you if your child tests positive.

4. What are the possible benefits for my child and other people in the future?

There may be no benefits for your baby. However, we think it will be helpful for you to know your child does not have this virus, and avoid more complicated testing for it at a later stage should your child have a confirmed hearing loss. Currently, screening tests for CMV are not routinely arranged for newborn babies in Victoria, and doctors are not able to make a diagnosis of congenital CMV early enough to offer treatment. If your child is tested to be positive for CMV, his/her hearing may need to be monitored closely, because we know that CMV-associated hearing loss can progress over time. In addition, further blood and urine testing, an eye examination and head ultrasound may help the doctor decide on the best management plan for your child.

We expect the main benefits to be for future babies in the program. If this project finds that early testing for CMV is possible, this extra test could be offered to all babies who do not pass their second hearing screen at all Victorian hospitals. If it is not possible to test for CMV early, we will know a different approach is needed.

5. What are the possible risks, side-effects, discomforts and/or inconveniences?

There are no risks to your baby when you take the saliva swab. Your baby can safely suck or chew the end of the swab stick without any harm. This saliva swab will be labelled with your baby's name and date of birth, and sent to the laboratory for CMV testing. The main inconvenience will be the time it takes for you and your baby to take part in the project. Should the information that your baby has a positive test cause you any kind of distress, we will have a dedicated team ready to support your family if required.

6. What will be done to make sure my child's information is confidential?

If you consent to this project we will collect and use personal information for research purposes, including information that you provide to VIHSP. Any information that can identify you or your child will be treated as confidential. We can only disclose the information with your permission, except as required by law.

The following people may access information collected for this project:

- The research team involved with this project
- VIHSP staff, including Early Support Services staff and Area Managers
- The Royal Children's Hospital Human Research Ethics Committee.

All original information collected in this project will be stored securely by the Murdoch Children's Research Institute (MCRI). The information will be entered into a secure database. We will remove identifying information, such as your or your child's name, and replace it with a special code number. Only the research team at MCRI can match your names to your code numbers, if this is needed.

Information which is collected as part of a research project must be kept for at least 7 years for participants aged over 18 years old. For participants aged under 18 years old, it must be kept until their 25th birthday. After this, we may securely destroy the research information we collect from you as part of this project.

In accordance with Australian and/or Victorian laws, you have the right to access and correct the information we store about you and your child. Please contact us if you would like to do this.

We plan to present the results of this project at conferences and in academic journals. We will only present group results so you and your child cannot be identified.

7. Will we be informed of the results when the research project is finished?

We will send you a summary of the HearS-cCMV project results when the project ends. The summary will give overall results of the project. We will never identify individual children or their families.

8. Who should I contact for more information?

If you would like more information about the project, please contact:

Name: The HearS-cCMV project team
Contact telephone: 0421 222 485
Email: hears.ccmv@mcri.edu.au

If you have any clinical or medical concerns which may be related to involvement in this project you can contact the principle study doctor

Name: Dr Rosalynn Pszczola
Contact telephone: WH switchboard: 8345 1333 and request pager: 761
Email: Rosalynn.Pszczola@wh.org.au

You can also contact the Manager of Western Health Office for Research or the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your child's rights as a research participant
- would like to speak to someone independent of the project.

Local Governance Office for Research

Name: Mr Bill Karanatsios, Manager Western Health Office for Research
Contact telephone: (03) 8395 8073
Email: ethics@wh.org.au

Reviewing Human Research Ethics Committee:

Name: Director of Research Ethics & Governance, The Royal Children's Hospital
Contact telephone: (03) 9345 5044

CONSENT FORM

HREC Project Number: HREC/18/RCHM/273
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Version Number: 6 **Version Date:** 01/04/2019

I consent to having information about the timeliness and outcomes of my child's CMV testing, hearing and cCMV-related medical appointments recorded.

- I have read this information statement and I understand its contents.
- I understand what my child and I have to do to be involved in this project.
- I have read the possible risks, side effects and discomforts and/or inconveniences section of this document.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee. I understand that the project and any updates will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.
- I understand that the CMV test results may be inconclusive if the saliva sample is taken after my child is 21 days of age.
-

Optional additional uses of my child's sample and data. Please tick one box on each line:

- | | | |
|-------------------------------|-----------------------------------|---|
| <input type="checkbox"/> I do | <input type="checkbox"/> I do not | consent for my child's saliva sample to be stored for use in future ethically-approved research related to cCMV or hearing loss |
| <input type="checkbox"/> I do | <input type="checkbox"/> I do not | consent to my data being shared anonymously with other researchers for use in future ethically-approved research |
| <input type="checkbox"/> I do | <input type="checkbox"/> I do not | consent to be contacted about future research projects related to cCMV or hearing loss |

Child's Name

Child's date of birth

Parent/Guardian Name

Parent/Guardian Signature

Date

Note: You must sign and date your own signature



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Child's Name	Child's date of birth	
Parent/Guardian Name	Parent/Guardian Signature	Date

Note: You must sign and date your own signature

Please complete the following details about your child and their last feed so we can complete the testing accurately:	
Last feed was a: Breastfeed <input type="checkbox"/> Bottle feed with breastmilk <input type="checkbox"/> Bottle feed with formula <input type="checkbox"/>	Date and time of last feed: __/__/____ at __: __am/pm