

PLAIN LANGUAGE STATEMENT

Project: General Practitioners' perspectives on universal screening for cytomegalovirus (CMV) infection in pregnancy

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1.1 Introduction

You are invited to take part in this research project, which is called "General Practitioners' perspectives on universal screening for cytomegalovirus (CMV) infection in pregnancy".

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research. Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Participation in this research is voluntary. If you decide you want to take part in the research project, you will be asked to consent within the online survey portal.

By indicating your consent, you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the use of your personal information as described.

You can download this consent form as a PDF from the online survey before you begin.

1.2 What is this research about?

Congenital cytomegalovirus infection is the most common infection affecting newborn babies. It is an important preventable cause of childhood disability, hearing loss, stillbirth and cerebral palsy. Universal serological screening for CMV in pregnancy has not been recommended to date in Australia. However, increasing evidence has shown the effectiveness of maternal antiviral therapies to reduce vertical transmission of CMV. In response to this, routine maternal serological screening for CMV is now recommended as best practice in Europe. In Australia, first trimester antenatal care is usually performed by general practitioners and so here we seek to understand General Practitioners' perspectives on maternal serological screening for CMV.

1.3 What will I be asked to do?

If you consent to participate, we will ask you to complete a questionnaire that we expect will take up to 10 minutes of your time.

1.4 What are the possible benefits?

On completion of the survey, you will have the option to go into the draw to win one of three \$100 gift cards. There will be no other direct benefit to you from your participation in this research. However, possible benefits may include improving education and information resources on CMV and informing any future implementation of maternal serological screening for CMV.

1.5 What are the possible risks?

There are no foreseeable risks associated with this study. Your responses to the questionnaire are de-identified and will therefore be confidential, and our study results will not be published in a way that could reveal your identity. We will not share or publish individual responses outside of the investigator group.

1.6 Do I have to take part?

No. Participation is completely voluntary. You can withdraw at any time prior to study completion. If you wish to have your questionnaire responses excluded from the final analysis, you can request this by sending an email to the study team at ese-cmv@unimelb.edu.au. Your decision whether to take part or not to take part will not affect your relationship with the study investigators or your relationship with The University of Melbourne.

1.7 Will I hear about the results of this project?

A brief summary of the research findings will be available on the study website ([Mercy Perinatal https://mercyperinatal.com/project/ese-cmv-study](https://mercyperinatal.com/project/ese-cmv-study)). It is anticipated that the results of this research project will be published and/or presented in a variety of scientific forums such as conferences and peer reviewed journals. Your questionnaire responses will be grouped together with other participants who are taking part in the project. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

1.8 What will happen to information about me?

By signing the consent form you consent to the research team collecting and using your survey responses for the research project. Data will be collected using secure platforms (REDCap) at the University of Melbourne. You will be assigned a unique study number and all data collected will include only the unique study number. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law. Upon completion of the research, your email address will be deleted from the dataset. However, if you consent to be contacted for future research projects, your email address will be retained for five years. De-identified data may be reused for future CMV-related projects conducted within five years of the study's completion, such as analysing the demographics of GPs who offer routine CMV screening. All data will be securely stored on a University of Melbourne server for five years before being permanently deleted.

1.9 Who is conducting this project?

This research is being led by Prof Lisa Hui who is an obstetrician at the Mercy Hospital for Women and a researcher at the University of Melbourne. The research team includes GPs, public health researchers and clinicians from Mercy Health, The University of Melbourne, Cerebral Palsy Alliance Research Institute, and The University of Sydney. This research has been funded by the Norman Beischer Medical Research Foundation. It is part of a larger project called the ESE-CMV study (Education, Serology & Evaluation to prevent congenital CMV).

1.10 Where can I get further information?

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact Dr. Tanya Tripathi at tanya.tripathi@unimelb.edu.au or any of the following people:

Research contact person

Dr. Tanya Tripathi

Research fellow, Dept of Obstetrics and Gynaecology, University of Melbourne, and Mercy Hospital for Women

Tanya.tripathi@unimelb.edu.au

Principal investigator

Prof. Lisa Hui

Dept of Obstetrics and Gynaecology, University of Melbourne and Dept of Perinatal Medicine, Mercy Hospital for Women

lisa.hui@unimelb.edu.au

1.11 Who can I contact if I have any concerns about the project?

This project has human research ethics approval from The University of Melbourne [2025-31079-65660-4]. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 1376 or Email: research-integrity@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence, please provide the name of the research team and/or the name or ethics ID number of the research project

Consent Form [REDCap]

General Practitioners' perspectives on universal screening for cytomegalovirus (CMV) infection in pregnancy

You are invited to complete a 10-minute survey as part of a research project aimed at understanding General Practitioners' perspectives on maternal serological screening for CMV.

Your survey responses are confidential, with no identifying information in the reporting of this study. Please read the participant information sheet and download a copy for your records [here](#).

- I consent to participate in this research project and confirm that I have read and retained a copy of the full participant information statement.
- I acknowledge the possible effects of participating in this research project have been explained to my satisfaction.
- I understand my participation is voluntary and that I am free to withdraw from this project anytime without explanation or prejudice.
- I understand that data collected in this research project may also be used in future projects that are closely related to this project.
- I understand the data from this research will be stored at the University of Melbourne and will be destroyed 5 years after publication.
- I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements.

Do you consent to taking part in this study?

* must provide value

I DO consent

I DO NOT consent

Optional Consent: Do you consent to being contacted about future research projects related to infections in pregnancy?

* must provide value

I DO consent

I DO NOT consent