



INFORMATION LEAFLET

Maternal health And Maternal Morbidity in Ireland (MAMMI) Study 5-Year Follow-Up Study

Research Tel: 087 118 6762. Research E-Mail: mammi@tcd.ie

Dear MAMMI Study Participant,

We would like to invite you to take part in the 5-year follow-up survey with the **Maternal health And Maternal Morbidity in Ireland (MAMMI)** study.

Before deciding whether you wish to take part, please read this information leaflet. If you have any questions about the study that are not answered by this information leaflet, please feel free to contact Deirdre Daly at the contact details on page 6.

Researchers with the School of Nursing & Midwifery at Trinity College Dublin, Dr Deirdre Daly, Dr Francesca Wuytack, Dr Patrick Moran and Dr Cecily Begley are conducting the MAMMI study 5-year follow-up and Second Baby follow-up (SIM) studies.

Please note, you do not have to take part in this research. You can change your mind about taking part in the Study at any time up to data anonymisation or publication, and you can opt-out without providing a reason.

Why are you doing the 5 year follow up?

The MAMMI Study was designed to gain knowledge on first time mothers' health and health problems during pregnancy and in the first year after the baby's birth. For some women, health problems might persist for longer than one year after birth and there is a lack of knowledge about the long-term consequences for women in Ireland. This follow-up study is designed to fill in some of the gaps and examine the health and health problems women are experiencing up to five years after the birth of their first baby.

The 5-year survey also asks if you have given birth to your SECOND CHILD within the past twelve months. If you have had your second child within the past twelve months AND you have consented to being contacted about future related research, you may be **invited** to complete the second baby follow-up survey.

Again, you do not have to take part in the second baby follow-up study.

Why have I received this information pack?

You have received this information pack because you were a participant in the MAMMI study when you had your first child five years ago and, at that time of joining the study, you consented to being contacted about taking part in future MAMMI study-related research. This information leaflet will tell you about the MAMMI 5-year follow-up study and what taking part involves.

What kind of questions will I be asked?

The MAMMI 5-year follow-up study will ask you questions on many of the same topics that were covered when you had your first child. In this survey, there will be questions about:



- General physical health and pain
- Mental health
- Urinary and anal incontinence
- Sexual health, relationships, and relationship issues
- Current living and work status

In addition, we have included three new sections to the MAMMI 5-year follow-up survey:

- Major life events
- Economic or financial impact of health problems
- Your opinions on data sharing

What are the potential RISKS for me and my child(ren)?

There are no foreseen risks with participation in the research study to you or your child(ren).

Are there any potential BENEFITS for me and my child(ren)?

This research study will describe women's health and health problems five years after their first baby's birth. The study will not benefit you individually but as many women are being invited to complete this survey, we hope that the information women provide will increase understanding of what causes some of these problems or makes problems persist long term for women.

Responses and comments made by women who completed the MAMMI surveys after the birth of their first child showed that taking part in the study alone helped some women become aware of health issues that might present after pregnancy. Completing the surveys also prompted women to seek professional assistance for various health concerns, made them feel less alone, and gave women a chance to reflect on their experiences.

For more information on women's experiences in taking part in the MAMMI Study please visit the MAMMI Study website, or read the research paper titled '*Stop, think, reflect, realize- first-time mothers' views on taking part in longitudinal maternal health research*' which is available to download for free at: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/hex.12861>

Who can participate?

Women who participated in the MAMMI Study and who consented to being contacted about future related research and give written consent to taking part in this follow-up study, by completing the enclosed consent form.

What does taking part in the Study mean for me?

We are asking you to complete ONE survey now that your first child is five years old. The survey should take about 45 minutes to complete. If you wish to take part, please return the SURVEY and COMPLETED CONSENT form to us in the FREEPOST envelope included in the pack. If you did not receive, or have misplaced, the FREEPOST envelope, consent form or the survey, please feel free to contact the team to request another.



Can I withdraw from the study?

You are free to withdraw from the study, without providing a reason, by ticking the 'withdraw' box on the front of the enclosed survey and returning it to us in the FREEPOST envelope, OR by contacting a member of our team via text or call on 087 118 6762, or by emailing the team at mammi@tcd.ie.

Please note that it will not be possible to withdraw your data after the data have been anonymised or before publication of results.

What happens to the information at the end of the study?

We will publish the findings from the study and give talks about the findings. It will not be possible to identify you or your answers in any of these publications or talks.

The information from the surveys may also be used in future research projects. However, the researchers will not contact you unless you give your consent to future contact.

We will also present the results to healthcare policy makers and service providers in Ireland, in order to raise awareness and improve knowledge of women's experiences. By doing this, we hope that the information you have given us will be used to shape and influence future services for women as they become mothers.

How can I see the results of the research?

Results from the MAMMI Study will be presented at national and international conferences. The findings will also be made available on the MAMMI website at www.tcd.ie/mammi

What do the options on the consent form mean?

The consent form asks you to sign your name to show that you agree to take part in this study.

The consent form asks if you to agree to the following options:

Paragraphs 1-4: these options are about ensuring that you understand what taking part means, that your participation is voluntary and that you are free to withdraw any time before the results are published.

Paragraph 5: this option guarantees that we will keep all study information secure and confidential.

Paragraphs 6-8:

- *Paragraph 6:* lets you agree to information collected from you as part of this Study being used for future research studies that have been approved by a Research Ethics Committee.
- *Paragraph 7:* lets you say if you want your personal details such as your name and address to be destroyed after this stage (MAMMI Study: 5-year follow up) of the research. If you say yes, the research team will not be able to contact you when this stage of the research is over to inform you of future developments.
- *Paragraph 8:* lets you agree to us keeping your personal details for five years after the end of this stage (MAMMI Study: 5-year follow-up) of the research. If you say yes, the research team will contact you and *invite* you to take part in future studies; you do not have to participate in them if you wish.
- *Paragraph 9:* lets you say if you consent to a member of the research team contacting you to invite you to take part in interviews relating to topics covered by the MAMMI Study.



Remember, you do not have to agree to any or all of these options and you may decide you do not wish to take part. However, if you do agree, you will help us to continue our study of the health problems experienced by pregnant women, mothers and their babies, and the longer-term impact on women's health and lives.

Data Protection Information

How will my information be used?

We will use your information to study the long-term health and health problems experienced by women in Ireland five years after the birth of their first baby.

Where you give consent, your information will be retained for a period of five years following completion of the MAMMI Study, and used for the purposes of future research related to the topics covered by the MAMMI Study surveys.

Five years after the Study has been completed, the electronic data will be anonymised and the paper copies of the surveys will be shredded and disposed of in accordance with Trinity College Dublin's procedures.

All future research will receive Research Ethics Committee approval, without the need for further consent from participants. All future data processed will relate to the content covered by the MAMMI surveys. The findings from the research study will be presented and published. It will not be possible to identify any woman individually in these presentations and publications.

Your data will be processed (collected, held, analysed) in compliance with **General Data Protection Regulation 2016 Article 6.1 (e):** *processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;* and **Article 9. 2 (j):** *processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89 (1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.*

Participants have the right to restrict or object to having their data processed, unless the request would make it impossible or make it very difficult to conduct the research. For example, it will not be possible to remove data after anonymization, analysis or publication.

Participants have the right to have their personal data deleted, unless their request would make it impossible or make it very difficult to conduct the research. For example, it will not be possible to remove personal data and maintain future contact with consenting participants.

How will you protect my personal information?

- We keep all the information you give us private and confidential.
- We give your survey information a unique number (a code), and we store your personal details and your code number securely and separately from the completed survey/s.
- Paper copies of the surveys are stored in locked cabinets, in a locked office where few designated people have access.
- We keep an electronic version of the information you give us on a Trinity College's main server. Only the research team have access to this information. We use password protection on every file containing personal data, encryption (special software to scramble the information so it cannot be read) and anti-virus software to protect the information on the computer.



Do you have procedures in place if there is a data protection breach?

In the unlikely event of a data protection breach, there is the potential for your personally identifiable information to become compromised.

We will hold and process all personal and sensitive information in compliance with the General Data Protection Regulation 2018 and the Health Research Regulations 2018. If a data breach should occur, the MAMMI Study team will follow Trinity College Dublin's Data Protection Breach procedures that comply with the General Data Protection Regulation 2018.

You may also read about our data protection procedures on our website at www.mammi.ie.

Who will have access to my information?

Only MAMMI Study team members who have a legitimate need to access data in the performance of their professional research duties will have access to your personal data. These members must sign a confidentiality agreement form, and, like all members of the University community, must abide by the Data Protection Policy, Data Protection Procedures and IT Security Policy. All MAMMI Study team members who are involved in carrying out research must enrol in, complete and successfully pass an assessed online training module entitled 'Data protection, IT security and Data Management'.

Will you share data from the MAMMI Study?

1. Where participants have given their consent to data sharing, anonymised data collected from the MAMMI study will be shared with the Maternal Health Study (MHS) research group: Murdoch Children's Research Institute, Australia.
2. Where participants have given their consent to data sharing, anonymised data collected from the MAMMI study will be shared with the Multidisciplinary Opinion and Democracy Research Group (MOD), Department of Political Science, University of Gothenburg, Sweden.

The data shared with the MHS research group and the MOD group will only contain the information collected from the paper surveys in an electronic format, it WILL NOT CONTAIN ANY PERSONAL DETAILS. In other words, the MHS and MOD researchers will receive anonymised data.

All personal identifiable information such as study numbers, names, or place names WILL BE REMOVED from the data shared with these researchers. This renders the data anonymised.

The MHS and MOD research groups will not receive any information that might directly, or indirectly, lead researchers to identify any individual participant.

Only members of the MHS and MOD research teams will have access to the data that the MAMMI Study team share with them. The anonymised data that they receive will also be protected using passwords and encryption (special software to scramble the information so it cannot be read) and anti-virus software to protect the information when used on their computers.

Participants have the right to refuse to have their data shared. Please note that it will not be possible to withdraw your data after the data have been anonymised or before publication of results.

Can I access my personal data?



You have the right to request access to a copy of your data, and you have the right to have inaccurate information about yourself corrected or deleted. Access and corrections to your data will be provided where this can be reasonably accommodated. You have the right to data portability, this means that you may request to have your data moved from one data controller to another.

Will my data be used for any automated decision-making, including profiling?

No, the MAMMI Study will not conduct any form of automated processing of personal data or profiling.

What do I do if I have a data protection complaint?

If you have a complaint regarding the MAMMI Study's protection of your data, you may contact the following people or departments:

The MAMMI Study Principal Investigator: Dr Deirdre Daly

Telephone number of principal investigator: 01-8962604 or 087 1186762

Email of principle investigator: mammi@tcd.ie

Trinity College Dublin Data Protection Officer:

Ms Jennifer Ryan

Postal Address:

Data Protection Officer

Secretary's Office, Trinity College Dublin,

Dublin 2, Ireland.

Email of TCD DPO: dataprotection@tcd.ie

Data Protection Commission:

Postal Address:

Data Protection Commission

21 Fitzwilliam Square South

Dublin 2, Ireland.

D02 RD28

Phone: +353 (0)761 104 800

+353 (0)57 868 4800

Website: <https://www.dataprotection.ie/en>

I have read the Information leaflet, how do I take part in the study?

Participating in the study means signing the consent form and completing the included survey form and returning both to us in the FREEPOST envelope provided. The survey takes approximately 45 minutes to complete. The second copy of the consent form in this pack is for you to keep.

1. Sign the consent form.
2. Keep a copy for yourself.
3. Post the original *signed consent* form and your *completed survey* using the stamped addressed envelope that came with this leaflet.

Further information

If you have any questions about the MAMMI Study or our data protection procedures, you can contact us for more information at 087 1186762 or mammi@tcd.ie. You can also visit the website at www.mammi.ie.

Kind Regards,

The MAMMI Team.