



Participant Information Statement

HREC Project Number:	79251		
Short Name of Project:	The Family Foundations Evaluation Study		
Full Name of Project:	The Family Foundations Evaluation: Strengthening parent mental health and family relationships in the early years of parenting		
Principal Researcher:	Associate Professor Rebecca Giallo, Senior Research Fellow		
Version Number:	1.3	Version Date:	24.11.2021

Thank you for taking the time to read this **Participant Information Statement and Consent Form**. We would like to invite you to take part in an evaluation study that is explained in this form.

This form is 5 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 study that is being conducted. It explains what the study involves. This information is to help you decide whether or not you would like to take part in the study. Please read it carefully. Before you decide if you want to take part or not, you can ask us any questions you have about the study. You may want to talk about the study with your family, friends or health care worker.

Taking part in the evaluation study is up to you

It is your choice whether or not you take part in the evaluation study. You do not have to agree if you do not want to. If you decide you do not want to take part, or decide to withdraw from the study at any time, it will not affect the treatment and care you get at Merri Health, your access to Family Foundations, The Royal Children's Hospital, or any other services.

Signing the form

If you want 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 taking part in the study

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

1. What is the evaluation study about?

Becoming a parent is a special time, but it can also be challenging at times. There are lots of things to adjust to including changes in roles and relationships, managing time for work and family, increased money pressures, and having less time for yourself. This can be stressful and can have an effect on family relationships.

Family Foundations was developed to support parents with the stress and challenges during pregnancy and after having a baby. Family Foundations is a 10-session program, which covers topics such as: managing stress; supporting each other as parents; ways to manage conflict and other problems that may come up; and ways to strengthen family relationships including parent-child relationships.

Family Foundations is designed for parents (and/or any other caregivers or parenting partners) to do together. The program can be delivered in three ways:

- **Home-based:** Family Foundations facilitators will come to your home to deliver the 10 sessions
- **Telehealth:** Family Foundations facilitators will deliver the 10 sessions via a teleconferencing platform to you and partner (and/or any other parenting partners)
- **Mixed Group, Home-Based & Telehealth:** This involves a combination of sessions with 2-3 other families at a Merri Health venue, sessions in your home, and sessions provided via a teleconferencing platform to you and your partner (and/or any other parenting partners).

Family Foundations is being offered to families by Merri Health. They will discuss which way to receive the program that might be best for you and your family.

The aim of our evaluation study is to find out whether Family Foundations helps to strengthen the health, wellbeing and relationships of parents and families in the short- and longer-term. We would also like to get parents' feedback about Family Foundations to help us improve it for families in the future.

Please note: You do not have to participate in this study to receive Family Foundations. Merri Health will still provide Family Foundations to you and your family even if you decide not to participate in this study.

2. Who is running the evaluation study?

The Family Foundations evaluation study is being done by the Murdoch Children's Research Institute and Merri Health. Associate Professor Rebecca Giallo is the Principal Investigator in the study. She is in charge of this study and the research team from MCRI. The researchers wrote the protocol for this study.

3. Why am I being asked to take part?

We are inviting you to take part in this evaluation study because you are a parent expecting a baby, and/or who has an infant aged 0-12 months and have been enrolled in the Family Foundations program by Merri Health.

Please note: You do not have to participate in this study to receive Family Foundations from Merri Health.

4. What do I need to do in this evaluation study?

You will be involved in this study for approximately 12-18 months. You will be asked to complete online surveys about your overall wellbeing and mental health, parenting, your relationship with your partner, and your child. You will be asked to complete surveys three times.

- Before you start Family Foundations (20 minutes)
- After you finish Family Foundations (15 minutes)
- 6 months after finishing Family Foundations (20 minutes)

This will help us understand whether parents and their children have experienced any changes in their mental health and wellbeing, their relationships, and their parenting after participating in Family Foundations. The second survey will also ask you about how satisfied you were with the Family Foundations program.

Some online survey questions may be sensitive, and you may wish to complete these in a private place. Specifically, some questions ask about your mental health, parenting, conflict within your family, health behaviours and stressful life events (e.g., loss of employment, family illness financial difficulties, and/or relationship difficulties). You may wish to clear your internet browser history once you have finished to keep your responses confidential from others who can access your device. You can stop the survey at any time and return later to complete it. If you wish to continue the survey later, you will be given a return code number. Please keep this number safe as you will need it to return and continue your survey. If you forget this number, please contact the research team as they will be able to send you your unique survey.

We are also asking for your permission to use information collected by the Merri Health Intake Team when you first enrol in Family Foundations. This includes information such as your gender, country of birth, education, past history of wellbeing difficulties, other stressors in your life, and number of children in your family. It will also include us asking the Merri Health Intake Team questions about when you start and finish the program, the number of sessions you completed, and how you had the program delivered (i.e., home-based, telehealth, mixed group, home-based & telehealth).

5. Other relevant information

Taking part in this evaluation study is completely voluntary. Choosing not to take part will not impact your access to the Family Foundations program provided by Merri health. During the study, you are free to access your usual health care such as a family doctor or counsellor.

6. Can I withdraw from the evaluation study?

You can stop taking part in the study at any time. You just need to tell us so. You do not need to tell us the reason why. If you leave the study, we will continue to use the information we have already collected about you. If you do not want us to use this information, please tell us. In this case, we will **stop using** your information. We will securely destroy the information as required by law. If you withdraw, it will not affect your access to other health care supports or your relationship with MCRI or Merri Health.

7. What are the possible benefits for me and other people in the future?

We cannot guarantee that you will get any direct benefits from this evaluation study. We hope that the study will benefit other families in the future. It could do this by helping us improve the Family Foundations program for other families and work out whether Family Foundations is beneficial in promoting parents' health, wellbeing and family relationships.

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

The main burden will be the time taken to complete the online surveys. To thank you for your time, we will offer a \$20 Supermarket voucher after you complete each of the three online surveys (before receiving Family Foundations, soon after finishing Family Foundations and 6 months after Family Foundations).

There is a small chance that you may feel uncomfortable or upset because you are taking part in this study. For example, in the online survey we ask about mental health difficulties, and your relationship and any conflict with your partner. If you feel uncomfortable or upset, you can take a break from the survey, skip a question, or choose to discontinue the survey. There are also details about support services on the survey.

9. What will be done to make sure my information is confidential?

We will collect and use personal and health information about you for research purposes. We will store your electronic information securely in an online database (REDCap) and on the MCRI internal server. These people may access your **identifiable** information:

- the research team involved in this study, who will come from MCRI and Merri Health.
- RCH Human Research Ethics Committee.

Students or other investigators involved in the evaluation study may have access to your **de-identified** information. This means they will not have access to your name or any other information that can identify you. We will replace your name with a code number and remove other identifying information. Only the research team on this study will be able to **re-identify** you by linking the code number to your name and other personal information.

We can only disclose identifying information about you with your permission, except as required by law – for example, if you tell us something that makes us worried about your safety or your children’s safety. In these circumstances we will be required by law to disclose this information to a third party to ensure that you or your child/ren are safe. We will discuss concerns about this with you prior to seeking additional support.

We will keep the information indefinitely after the study is completed. You have the right to access and correct the information we collect and store about you. This is in line with relevant Australian and/or Victorian privacy and other relevant laws. Please contact us if you would like to access this information.

At the end of the evaluation study, we may present the results at conferences. We may also publish the results in medical or academic journals. We will do this in a way that protects your privacy. It will not be possible to identify you in anyway.

10. Will I be informed of the results when the evaluation study is finished?

At the end of the study, we will send you a final letter. This letter will explain what we found out in this study. The letter will not have any information specifically about you.

11. Who should I contact for more information?

If you would like more information about the evaluation study, please email:

familyfoundations@mcri.edu.au

Or call us:

Dr Grace McMahon

Research Coordinator

Murdoch Children’s Research Institute

Ph: 0431 101 643

Email: grace.mcmahon@mcri.edu.au

In the case of an emergency, please contact:

Name: A/Prof Rebecca Giallo

Contact telephone: 0431 101 643

Email: rebecca.giallo@mcri.edu.au

You can contact the Director of Research Ethics & Governance at The Royal Children’s Hospital Melbourne if you:

- have any concerns or complaints about the study

- are worried about your rights as a research participant
- would like to speak to someone independent of the study

The Director can be contacted by telephone on (03) 9345 5044.

CONSENT FORM

HREC Project Number: 79251
Short Name of Project: The Family Foundations Evaluation Study
Version Number: 1.3 **Version Date:** 24.11.2021

We are seeking your consent to participate in the evaluation study electronically. To give consent for you to participate, please read and ensure you understand the following:

- I have read this information statement and I understand its contents.
- I understand what I have to do to be involved in this evaluation study.
- I understand the risks I could face because of my involvement in this evaluation study.
- I voluntarily consent to take part in this evaluation study.
- I have had an opportunity to ask questions about the evaluation study and I am satisfied with the answers I have received.
- I understand that this evaluation study has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee. I understand that the study is required to 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.

Please tick the box below if you consent to participate in the Family Foundations Evaluation Study being conducted by the Murdoch Children’s Research Institute

I give consent for you to contact me using the following details:

- First name: _____
- Middle name: _____
- Last name: _____
- Phone number: _____
- Email: _____