Participant Information and Consent Form
Survivor Participants

Full name of project	A Double blind Randomised Controlled Trial of a Paediatric Fertility Preservation Decision Aid in Parents and Children, Adolescents and Young Adults (CAYA) Cancer Survivors
Short Title	FOCUS: Fertility Options for Children and Young Survivors Trial
Principal investigator	Associate Professor Yasmin Jayasinghe
Project number	ERM 107901

What am I being invited to do?

We are inviting you to take part in our project. We want to develop online information for young people such as yourself who received cancer treatment when they were under 25 years of age. The online information is about reproductive health after cancer treatment. We want to give young people such as yourself useful information about puberty and development, fertility, and sexual health.

If you take part, we will ask you to do three online sets of questionnaires. The questionnaires ask you to think about how well our information about reproductive health suits your needs.

Around 360 people will take part in this project. They will include cancer survivors and parents of cancer survivors.

Please read this information and ask us any questions. You can also talk to someone you trust, like a family member, friend, or your doctor. You can take time to make up your mind. You get to decide whether this project is right for you.

What is the purpose of this project?

In this project, we want to produce online information resources that help young people such as yourself make informed decisions about their reproductive health.

We are comparing two sets of information resources. We will test them with participants and compare which information resource is better. You will be randomly allocated to a group by a computer program. The researchers will not know which group you are in. At the end of the project, we may give you both sets of information resource.

As you may know, some cancer treatments can affect hormones and reduce fertility. Many cancer survivors can have natural pregnancies. But others might be advised to freeze reproductive tissue or eggs or sperm to try to protect fertility. Decisions about fertility can happen arise at all stages of the treatment journey (diagnosis, during treatment or after treatment).

Fertility preservation is a relatively new service and we are still learning about what works. Given the changing knowledge in this area, it is important for us to develop useful, evidence-based information for young people such as yourself.

In addition, after treatment other questions may arise about development, hormone therapy, safe respectful relationships, sexual health, how to assess fertility and options for achieving parenthood.

Do I have to take part and can I change my mind?

Taking part is up to you
You get to decide whether you take part in this project. You can say yes or no.
Your decision will not affect your relationship with The Royal Children's Hospital / Murdoch Children's Research Institute (MCRI). It will not impact your medical care in any way.

You can change your mind at any time
If you do take part, you can stop at any time. If you want to stop, please tell someone in the project team. You do not have to tell us the reason.

Once you stop taking part, we will not do any more project visits. However, we will keep the information we have already collected about you. This is so we can measure the project results properly. Please only join this project if you are happy with this approach.

The project might stop for other reasons

We might need to stop the project while you are taking part. If this happens, we will explain the reasons to you.

We may also ask you to stop taking part in the project if it is no longer in your best interests. If this happens, we will discuss this with you.

What do I have to do if I take part?

If you meet the eligibility and take part in this project, we will email you three sets of questionnaires, along with different online resources. We will ask you to fill out the first set of questionnaires before you review the resources then fill out two sets questionnaires 8 weeks and 6 months after you have received the link for the information resource. Each set of questionnaires will take up to 40 minutes to fill out. You can do this on your phone or electronic device.

Once you have signed this consent form, we will send the first set of questionnaires; these will give us general information regarding your cultural and social background and other characteristics related to your cancer treatment and journey. This will help us to understand your particular circumstances and experiences regarding your medical treatment as well as how you receive information which can influence your decision-making process such as outlook of life and depression (if present). We are also interested to know about your level of fertility information knowledge since you have completed your cancer treatment. Some of these questions may cause distress as it asks you about information at the time of cancer diagnosis, if this occurs the research team will provide guidance and assistance.

After you complete the questionnaires, you will receive the link to review the fertility information resource. You will be randomly assigned (similar to tossing a coin) to review two different types of information resources.

The second round of surveys will be provided after you review the information resources, you will have 4 weeks to complete them, and the research team will follow up twice during this timeframe. This time we will assess the level of unmet fertility information needs, as well as your satisfaction with the fertility resource information provided.

The last set of questionnaires will be sent 6 months after you have been allocated to a group and you will also have 4 weeks to complete them. The research team will follow up twice within this time frame.

Your time and expenses

You will need to spend about two hours filling out the questionnaires for this project (40 min per set). After you have filled out all three sets of questionnaires, we will give you $30 gift voucher to thank you for your time.

What are the benefits of taking part?

The project may not provide direct benefit to you. By taking part, you will help the researchers understand more about fertility information and needs in cancer survivorship. This knowledge may help people and guide care in the future.

What are the risks and discomforts of taking part?

Taking part in the project might raise uncomfortable emotions or anxiety about your cancer journey or fertility. If participation in the study raises specific concerns, the research team can link you into relevant support services.

The contact details for advice on support services or if you have any questions about the research being conducted are:

Non-Emergency Support:

- Your **general practitioner** (GP) or
- **Beyond Blue** 24-hour phone-based counselling service on 1300 224 636
- **Community Support Services such as CanTeen**
- *Alternatively, the* ***Research Team (Mahnaz Sharifi-study coordinator)*** *on email FOCUS-trial@unimelb.edu.au, and we will direct you to appropriate support.*
- *Or* **Senior Associate Investigator A/Prof. Michelle Peate (**Responsible Researcher). Tel: +61 3 8345 3792 email: mpeate@unimelb.edu.au.

If you would like more information in regards to medical care please contact

- Your **general practitioner (GP)** *or*
- **Principal Investigator** A/Prof. Yasmin Jayasinghe (Responsible Researcher). Tel: 0383453721; email: FOCUS-trial@unimelb.edu.au

How will my information be used for this project?

This section tells you how this project will collect, store, use, and share and/or dispose of your information. If you do not want us to collect this information, you cannot participate in this project.

Collecting your information

We will collect information from you for the project such as:

- Basic personal information, including names, dates of birth, contact details
- Health information such as health data, including information about your condition and your medical history
- Website activity – When you review the information resource website, we will collect information like the pages visited and the time spent on the site. This will help us understand how people are using the information resource website.

Please know that we will not share this information in any way that could identify you personally.

Keeping your information safe

To keep your information safe, we will:

- follow all relevant privacy requirements
- store information securely on an electronic database under the Murdoch Children's Research Institute (MCRI) servers.
- take steps to prevent anyone from accessing information that identifies you unless they are authorised to do so, such as the project sponsor.
- give information and samples a code and keep them separate from your name or contact information.

You can ask us to tell you what information we have collected about you as part of this project. If your information is not correct, you can also ask us to change it. If you have any complaints about how we are managing your personal information, you can contact the RCH research office, details on page 6.

We will keep your information for 15 years. After that we will permanently remove any information that directly identifies you but keep the deidentified information

Publishing project information

We will share certain information from this project so that others can use the findings. This project information will not identify you individually, it is limited to the summary of the study results. We will make this project information available through journal articles and conference presentations. **By being in this project, you agree to let us share the findings.**

How will my information be shared for future research?

Sharing information

To help improve science, medicine and public health, we may share your information (without your name or personal details) with funders, research projects, biobanks, medical journals or data research repositories. Some of these organisations may be located overseas. **Any data that we send overseas may not be protected by Australian laws and regulations.** By signing this consent form you are giving us permission to do this.

If we share your information, we will remove your personal details such as your name, date of birth and address. We will give this information a special code number so your identity stays private. We will put strong security measures in place, so no can identity you. These security measures include

- Your special code number will be kept separately from your personal information and the data we collect about you.

Despite our best efforts, there is a small chance that you could be re-identified by someone outside of this research project. In the unlikely event that this happens, someone from the research team will contact you. If, at any point, you think that you may have been re-identified, please let us know.

Future funding

We may apply to government organisations or commercial companies for funding for this project. If we get funding, we will only use aggregate data, no individual data will be available. If so, we will do this in a way that protects your privacy. We will also let you know that we have done this.

Who is running and paying for this project?

This project is being run by The University of Melbourne initiated by A/Prof Yasmin Jayasinghe. It is sponsored by MCRI. The site has a Medical Research Future Fund grant to run this project.

Who has reviewed and approved this project?

The Royal Children's Hospital HREC has approved this project. This is an independent committee that makes sure that this project meets Australian ethical standards for research that involves people.

Comments or complaints about how this project is being run

If you have any comments or complaints about this project, please contact the Director of Research Operations at The Royal Children's Hospital.
You can phone the Director on (03) 9345 5044 or email them at rch.ethics@rch.org.au.

Where can I find more information?

Thank you for taking the time to read this information about our project. You can contact a member of the project team at any time to ask questions.
Name: A/Prof Yasmin Jayasinghe (Project Lead)
Contact telephone: 0383453721
Email: FOCUS-trial@unimelb.edu.au

You can find out more information about the project by visiting our website/scanning the QR code below/asking us <to be inserted>

Signature Page (E-Consent)

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If you choose to participate in this research, kindly read through and check all the boxes below:

☐ I freely agree to take part in this project

☐ I understand that I can stop taking part in the project at any time

☐ I have read, or have had read to me, the information provided about this project and understand what is involved including the use of my personal information

☐ I have had the opportunity to consider the information, ask questions and am satisfied with the answers I received

Do you consent to participate in this study?

a. Yes
b. No→ the following text will appear.

Thanks for your time.

If Yes,
Person taking part in the project

Signature: ____ Date: ______________

Name: ____

Person conducting the informed consent discussion

I have explained the research project, its procedures and risks to the potential participant and I believe they have understood that explanation.

Signature: ____ Date: ______________

Name: __________________________________ >

Witness (where decision-maker has required assistance to read this form)

Signature: ____ Date: ______________

Name: ___________________________________ >

Each person must sign and personally date this consent form

“Submit”