

Information statement and consent form

HREC Project Number:	33064		
Research Project Title:	Fertility preservation measures at The Royal Children's Hospital, Melbourne		
Principal Researcher:	Dr Yasmin Jayasinghe		
Version Number:	6	Version Date:	25/11/2019

Dear Participant

Some treatments may be associated with loss of fertility in the future. When you are first told that you have a serious medical condition, it is a very busy and stressful time, and often discussions about future fertility are very emotional. At The Royal Children's Hospital (RCH), we are able to offer some fertility preservation procedures for children and adolescents in the hope that it may enable future childbearing. However, some of these procedures are experimental and we do not know how successful they are in terms of achieving a pregnancy. You are invited to take part in this research project as you have been under the care of The Royal Children's Hospital and have had discussions regarding fertility.

We wish to assess outcomes regarding fertility irrespective of whether you had a fertility preservation procedure or not. Monitoring may include hormonal function and any attempts at having children. This is happening as part of a research study of fertility consultations at our centre.

This research is funded by The Royal Children's Hospital and The University of Melbourne.

We are inviting you to take part. In this research we will access and use information collected as part of your routine treatment and care, for research purposes: this includes information from your hospital medical record, results of tests, access to your pathology samples for reanalysis information related to surgical procedures, treatment and fertility preservation discussions and procedures (if applicable).

We would also like you to consider these optional parts of the research:

1. If you were referred to another centre for discussion of fertility preservation, such as Melbourne IVF, the Royal Women's Hospital, we are also asking permission to review the medical records at that centre.
2. In order to get more information about fertility outcomes in the future, such as attempted IVF procedures, results regarding hormone function, we would like your permission to allow us to link to other databases (listed below) to collect additional information:
 - a. The Royal Women's Hospital Melbourne IVF database at the Department of Reproductive Services
 - b. Births, Deaths and Marriages Register
3. We may undertake other research in the future. We would like your permission to contact you about future research. We will collect contact details from you as well as for a relative or close friend who may help us if we are unable to contact you directly.

We cannot promise that you will get any personal benefits from this research. However, we hope the information we get may help other children, adolescents and young people diagnosed with cancer in the future.

We do not expect this research to cause any risks or distress to you.

Any information we collect that is used for research purposes that can identify you will be treated as confidential. We can disclose the information only with your permission, except as required by law.

All information will be stored securely in the Gynaecology department at the RCH. The following people may access information collected as part of this research project:

- the research team involved with this project
- the RCH Human Research Ethics Committee

The information will be re-identifiable. This means that we will remove your name and give the information a special code number. Only the research team can match your name to the code number, if it is necessary to do so.

We are required to keep information collected for research purposes for 7 years after your 18th birthday. However, the information in this research may be securely stored for an indefinite period of time.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access the information.

When we write or talk about the results of this project, information will be provided in such a way that you cannot be identified.

At the end of the project, we will send you a summary of the results. This will be of the whole group of participants, not your individual results. Please note this project may not finish for a number of years.

Participation in this project is voluntary. You do not have to take part if you do not want to. You can withdraw from the project at any time, without giving a reason. We will not use any of your information for this research if you withdraw. If you do not take part, or withdraw, it will not affect access to the best available treatment options and care from the RCH or RWH.

If you have any questions, or would like further information about this project, please contact Dr Yasmin Jayasinghe, Gynaecologist Royal Children's Hospital by email at Yasmin.jayasinghe@unimelb.edu.au, or on (03) 8345 3721; or Dr Lisa Orme, Oncologist Children's Cancer Centre by email at lisa.orme@rch.org.au or on (03) 9345 5656; or Dr Ken Pang, Gender Service by email at ken.pang@mcri.edu.au or on (03) 93455986

Yours sincerely

Principal Investigator

Dr Yasmin Jayasinghe
Clinical Lead Fertility Preservation Service
The Royal Children's Hospital

If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact Director, Research Ethics and Governance, The Royal Children's Hospital Melbourne on telephone: (03) 9345 5044.

CONSENT FORM

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- I have read, or had read to me in my first language, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my involvement in this project.
- I voluntarily consent to take part in this research project.
- I have had an opportunity to ask questions 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 and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – including all updates.
- I understand I will receive a copy of this Information Statement and Consent Form.

OPTIONAL CONSENT

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to the investigators viewing my medical records at other centres where fertility preservation discussions or procedures took place
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to data linkage with The Royal Women's Hospital Melbourne IVF database and the Births, Deaths and Marriages Register
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to be contacted about future research projects that are related to this project

Participant Name

Participant Signature

Date

Declaration by researcher: I have supplied an Information Statement and Consent Form to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name

Research Team Member Signature

Date

Note: All parties signing the Consent Form must date their own signature.