

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: 9 **Version Date:** 25/11/2019

Dear Parent

Some treatments may be associated with loss of fertility in the future. When your child first received a significant medical diagnosis 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.

We wish to assess outcomes after fertility preservation measures, such as hormonal function, and any attempts at having children. This is happening as part of a research study of fertility so that we may report outcomes of all fertility preservation consultations at our centre.

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

We are inviting your child to take part. In this research we will access and use information collected as part of your child's routine treatment and care for research purposes: this includes information from your child's hospital medical record, results of tests, access to their 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 the following optional parts of the research:

1. If you or your child were referred to another centre for discussion of fertility preservation for your child, such as Melbourne IVF, the Royal Women's Hospital, we are also asking permission to review the medical records at that centre (both yours and or your child's).
2. In order to get more information about fertility outcomes in the future, such as attempted IVF procedures, natural births, results regarding hormonal function and outcomes of potential future pregnancies or births, 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 and your child about future research. Any information we send you does not oblige you to take part in

any 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 your child will get any personal benefits from this research. However, we hope the information we get may help other children in the future.

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

Any information we collect that is used for research purposes that can identify your child 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 child's name and give the information a special code number. Only the research team can match your child's name to their code number, if it is necessary to do so.

We are required to keep information collected for research purposes for 7 years after a participant's 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 your child. 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 your child 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 child's individual results. Please note this project may not finish for a number of years.

Participation in this project is voluntary. If you have given consent on behalf of your child to participate in the research, we will contact them at 18 years of age or over to ask permission to continue to use this information for research purposes. Your child does not have to take part in the research if you do not want them to. You may decline on behalf of your child. We would still like to contact your child when they are 18 years or over, to give them the opportunity to participate. If your child does not take part, or withdraws, it will not affect access to the best available treatment options and care from the RCH.

If you have any questions, or would like further information about this project, please call 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) 39455986.

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 child's involvement in this project.
- I voluntarily consent for my child 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 or my child's medical records at other centres where fertility preservation discussions or procedures for my child 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

Child's Name

Parent/Guardian Name

Parent/Guardian 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 child's 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.