CONSENT BY PARENT OR GUARDIAN TO COLLECTION AND STORAGE OF GONADAL TISSUE

Name of Young Person: _____DOB: _____MIVF No: _____

EPIC No: _____

Names of Parents / Guardians: _____

Address: _____

Phone numbers: _____

Email: _____

A. COLLECTION, CRYOPRESERVATION AND STORAGE OF GONADAL (ovarian and testicular) TISSUE

I wish to have a sample of my child's testicular/ovarian tissue collected and stored for their possible future use. I understand that:

1. My child's testicular/ovarian tissue will be obtained surgically and then passed to Melbourne IVF(MIVF)/ Royal Women's Hospital (RWH) laboratory, where it will be cryopreserved (frozen) and stored for their future use in attempting to establish a pregnancy or hormone replacement. A sample of tissue will be sent for pathology testing and quality assurance testing. Any mature sperm/eggs found will be dissected and cryopreserved separately for future use.

2. I understand loss or damage to gonadal tissue in handling, transport or storage is a risk despite all reasonable efforts made by all participating parties (including site of collection, transport and freight companies, MIVF/RWH)

3. To achieve a pregnancy, IVF-related procedures may have to be used. If my child elects to undertake such procedures in the future, they will have to comply with the relevant legislation at that time.

4. I consent to the continued storage of my child's testicular/ovarian tissue until they are legally able to make their own decisions. Once 18, they will be able to make their own decisions about the future storage and use of the tissue.

B. LIMITATIONS of the PROCEDURE

I understand and acknowledge the collection, cryopreservation and storage has the following limitations;

1. Some or all of the tissue obtained may not be suitable for cryopreservation. In that event, part or all of the tissue obtained will be discarded.

2. If testicular/ovarian tissue is collected, cryopreserved and stored, no guarantee or assurance can be given that this tissue will be thawed successfully. Furthermore, the thawed tissue may not be suitable for subsequent use in attempting to establish a pregnancy.

3. I understand that currently storage of tissue from children is regarded as experimental. There are no births reported from prepubertal storage of testicular tissue.

4. I understand that successfully thawed testicular/ovarian tissue may not result in successful fertilisation, pregnancy and live birth and that no guarantee can be given by MIVF or the RWH in that regard.

C. MY RESPONSIBILITIES

I confirm that the personal details I have provided are correct. I agree to advise M IVF as the unit responsible for storage in writing of any future changes.

I am aware that there may be fees for processing, freezing and storage of my child's tissue/sperm/eggs in the future and I agree to pay these fees when required.

I understand and acknowledge that in the event I am not able to be contacted at the address I have provided, or if the fees are not paid in full, RWH/MIVF may, at its discretion, discard my child's testicular/ovarian tissue with no further notice to me.

D. LENGTH OF STORAGE

I understand that the Victorian Assisted Reproductive Treatment (ART) Act (2008) specifies a maximum time permitted for which my child's testicular/ovarian tissue may be legally stored. In that regard;

- Under the Assisted Reproductive Treatment (ART) Act 2008 (Vic), my child's gonadal tissue can be stored for up to 20 years;
- To extend the storage period beyond 20 years, my child will need to make an application to the Victorian Patient Review Panel (PRP) prior to that time for permission to do so. My child will be responsible for making this application.
- At the end of the storage period, MIVF and RWH are required by law to remove the tissue from storage and dispose of it unless the PRP has granted written approval to extend the storage period.

E. WE ARE REQUIRED BY LAW TO DISCUSS WHAT HAPPENS IN THE EVENT OF YOUR CHILD'S DEATH.

In the event of my child's death before the age of 18, with testicular/ovarian tissue remaining in storage:

- I understand that the stored tissue will be, by law discarded. There may be an opportunity to donate the tissue to research if legislation changes in the future.
- I understand that I am responsible for notifying RWH/M IVF in the event of my child's death.
- I understand that in the event of my child's death, the treating hospital may contact MIVF/ RWH to relay this information

F. USE OF PERSONAL HEALTH INFORMATION

1. I understand that site of collection, RWH and MIVF are bound by the requirements of the applicable privacy laws with respect to the management of patient health information and I may request a copy of the MIVF Privacy Policy.

2. I understand that my child's treatment will be provided by a multi-disciplinary team, and that all members of the team will have access to their health records, as required.

3. I understand that MIVF is required to provide statistical data to meet statutory licensing and regulatory requirements under the ART Act (2008) and also to the Fertility Society of Australia's Reproductive Treatment Accreditation Committee (RTAC) for accreditation purposes. I understand that as part of the licensing and accreditation process, MIVF may be required to make my child's records available to independent audit teams, who are subject to strict confidentiality constraints. On their behalf, I give permission for the personal health information held by MIVF to be used for these purposes.

   On their behalf, I also give permission for MIVF to use personal health information for research and quality assurance purposes. I understand that no information will be disclosed to third parties for these purposes without first being fully de-identified.

G. CONSENT

The treatment and procedures including possible benefits and limitations in relation to the collection, cryopreservation and storage of my child's testicular/ovarian tissue have been explained to us by

Dr _____ Signed _____
Name of treating Doctor *Medical Practitioner*

As far as I am aware, my child is not opposed to the collection, cryopreservation and storage of their testicular/ovarian tissue.

I _____ (*name of parent or guardian)* consent to the surgical removal, cryopreservation and storage of testicular /ovarian tissue obtained from

_____ (name of young person)

Signed:_____ _____
Parent/guardian *Witness*

Date: _____

Signed:_____
Patient

I, _____, certify that there is a reasonable risk that the patient named
Name of treating Doctor

_____ may become infertile before reaching adulthood.
Name of the child

Signed: _____ Date: _____
Medical Practitioner