

Storage of Ovarian Tissue Consent Form - Minor

Patient Details:

Full Name of Patient: _____

IVF No: _____ Date of Birth:/...../.....

Address: _____

_____ Postcode: _____

Telephone No: (H) _____ (W) _____ (M) _____

Mature minor? YES NO (TO BE COMPLETED BY MONASH IVF SPECIALIST ONLY)

Where a Monash IVF doctor has ticked 'YES' (ie. the patient has been classed as a mature minor), the patient may consent to the procedure and therefore complete this consent form themselves. It is recommended that Parents/Guardians also acknowledge their agreement by signing this form.

Where a Monash IVF doctor has ticked 'NO' (ie. the patient has **not** been classed as a mature minor), the patient's parent or guardian must complete this consent form on the patient's behalf.

Name of Parent/Guardian:

Full Name: _____

Relationship to Patient: _____

Address: _____

_____ Postcode: _____

Telephone No: (H) _____ (W) _____ (M) _____

Referring Doctor's Name: _____

Address: _____

_____ Postcode: _____

Telephone No: _____

Reason for Ovarian freezing and Storage: (Please tick)

Medical storage Diagnosis: _____

Treatment: _____

Appendix 15

I have been given a Plain Language Statement which I have read and understood about the Ovarian Tissue collection procedure and subsequent storage of my/the Ovarian Tissue. This information has been explained to me by the IVF Specialist.

I have had the opportunity to have my partner, a member of my family or a friend present with me while the procedure was explained to me.

Signature of Patient:

(Mature minor)

Date:/...../.....

AND

Signature of Parent/Guardian:

Date:/...../.....

Statement of Supervising IVF Specialist

I, Dr. _____ (*Supervising IVF Specialist full name*) agree

that I have discussed with _____

(*patient's and/or parent/guardian's full names*)

ovarian tissue collection, freezing and storage, including the current success rates of resulting pregnancies and the possible risks and complications which could arise.

Signature: _____

(*IVF Specialist*)

Date:/...../.....

Section A - Consent

I give my consent for the Ovarian Tissue retrieval procedure, freezing and storage of my Ovarian Tissue at Monash IVF.

I understand, acknowledge and agree as follows:

- a) There is no guarantee or assurance by Monash IVF, its servants or agents that my/the Ovarian Tissue, prepared and frozen in liquid nitrogen.
- b) There is no guarantee or assurance by Monash IVF, its servants or agents that my/the Ovarian Tissue, stored in liquid nitrogen or by any other means now or in the future, will, when thawed, fertilise or produce a pregnancy;
- c) Fees are charged for Ovarian Tissue collection, freezing and storage at private rates established by Monash IVF (and its Pathology provider). I understand that Monash IVF will forward regular invoices for storage fees. Failure to respond to these accounts may result in requirement for back payment if I/_____ return to use my/the stored Ovarian Tissue.
- d) Storage fees will be charged in 6-month blocks or part thereof. Please notify the staff if you do not wish to continue storing your Ovarian Tissue or an invoice will be issued for 6-month storage fees.

Signature of Patient:

(Mature minor)

Date:/...../.....

AND

Signature of Parent/Guardian:

Date:/...../.....

Section B - Storage Regulations:

The length of time that you can keep your Ovarian Tissue in storage is determined by the ART Act 2008 in Victoria, and by the NHMRC *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, June 2007*, in all other States.

In Victoria:

The *Art Act 2008* provides that Ovarian Tissue must not remain in storage in excess of **ten** years, except with the approval of Monash IVF. Monash IVF will attempt to contact you to determine whether you wish to apply for an extension in the storage time, when the time limit is due to expire. After that time, applications to Monash IVF for a further extension of storage is your responsibility. If no alternative arrangements have been made by you and Monash IVF has made all reasonable attempts to contact you, then Monash IVF will apply to the Patient Review Panel for authorisation to dispose of your/the Ovarian Tissue.

You will have been advised of any storage details following treatment and Monash IVF will attempt to forward correspondence regarding storage options at regular intervals. However, **it is your obligation and responsibility** to inform Monash IVF in writing of any changes to your current address and any changes in your directives concerning your/the stored Ovarian Tissue.

In all other states:

Ovarian Tissue maybe kept in storage for a maximum of 10years. A request to extend the storage time must be made in writing to your Monash IVF clinic.

e) I have read the above information and understand the legal (Victoria) / ethical (all other States) requirements in relation to storage of Ovarian Tissue.

f) Whilst I understand that Monash IVF will exercise reasonable care and skill in respect of its procedures for Ovarian Tissue storage and in the implementation of those procedures, I acknowledge that Monash IVF, its servants and agents take no responsibility for any loss of viability of my/the Ovarian Tissue or any damage (including irreversible damage) which may occur to the Ovarian Tissue whilst storage at Monash IVF or elsewhere, and I absolve Monash IVF, its servants and agents from any liability in respect of such loss or damage.

Signature of Patient:

(Mature minor)

Date:/...../.....

AND

Signature of Parent/Guardian:

Date:/...../.....

Section C - Consent to Treatment and Use of Products Derived from Biological Tissue Including Human Blood or Plasma

Protein in one form or another is a necessary component of all media used to culture cells, including Ovarian Tissue.

The medium used to freeze Ovarian Tissue contains the protein albumin. Albumin is a protein fraction extracted from human blood. It is obtained in bulk from the Red Cross in the United States and repackaged for use as a culture medium supplement, and has been screened for a range of known infectious conditions in the same way that all blood transfusion products are screened. The use of albumin as the protein source in IVF culture media is a common practice occurring throughout the world. The culture media containing the albumin has been approved by the Therapeutic Goods Administration (TGA) here in Australia and it has been approved by the Federal Drug Administration (FDA) in the USA. It is a pharmaceutical quality product originally approved for transfusion use and conforms to all the same requirements as albumin products supplied by the Red Cross. Although there have been no reported infections from the use of human serum albumin, it is a blood derived product and therefore the potential for infection cannot be completely eliminated.

If you have any questions or queries, please discuss them with your IVF Specialist.

I have read and understood the above statement and agree to the use of culture medium containing Human Serum Albumin for the freezing of my/the Ovarian Tissue.

Whilst I understand that Monash IVF will exercise reasonable care and skill in respect of its procedures for Ovarian Tissue storage and in the implementation of those procedures, I acknowledge that Monash IVF, its servants and agents take no responsibility for any loss of viability of my/the Ovarian Tissue or any damage (including irreversible damage) which may occur to the Ovarian Tissue whilst storage at Monash IVF or elsewhere, and I absolve Monash IVF, its servants and agents from any liability in respect of such loss or damage.

Signature of Patient:

(Mature minor)

Date:/...../.....

AND

Signature of Parent/Guardian:

Date:/...../.....

Section D - Transport of Ovarian Tissue between Monash IVF Centres

Occasionally, Monash IVF has a need to transfer Ovarian Tissue between sites to allow treatment at different affiliated Monash IVF facilities. Such transportation may involve fresh or cryopreserved (frozen) material and takes place in special transport containers handled by appropriately trained staff or professional courier services.

g) I consent to Monash IVF to transport Ovarian Tissue between affiliated Monash IVF Centres / Satellites as required for treatment.

h) I agree that neither the sending nor the receiving unit is responsible for or liable for the safety and integrity of the Ovarian Tissue during transportation or for the condition upon arrival.

i) I agree that accidents beyond the control of all parties involved can occur during transportation resulting in the loss of viability of the Ovarian Tissue.

j) I agree that in the absence of any criminal negligence the carrier is not liable for the condition of the Ovarian Tissue upon delivery to its destination.

Signature of Patient:

(Mature minor)

Date:/...../.....

AND

Signature of Parent/Guardian:

Date:/...../.....

Section E - Contact Responsibilities

In accordance with current regulations and Monash IVF Policy, the following information must be recorded.

It is your obligation to inform Monash IVF with changes of address. Any changes must be submitted to the IVF Clinic in writing.

Signature of Patient:

(Mature minor)

Date:/...../.....

AND

Signature of Parent/Guardian:

Date:/...../.....