

IN VITRO FERTILISATION (IVF) & INTRACYTOPLASMIC SPERM INJECTION (ICSI) INCLUDING FREEZING OF EMBRYOS CONSENT FORM

Patient Name DOB

Partner Name(if applicable) DOB

Patient Number

I/ We request that the medical and embryology team at CREATE Fertility assist us to achieve a pregnancy by treatment with IVF.

1. After full discussion with Dr I/ we are given to understand that the treatment consists of some, or all, of the following steps:

- (a) Superovulation using ovarian stimulating drugs (where relevant) or the administration of such drugs to the woman as required this has been explained to me/us.
- (b) The collection of egg(s) by ultrasound guided needle aspiration techniques.
- (c) Fertilisation of any egg(s) by IVF or ICSI
- (d) Transfer of selected embryo(s) into my/my partner’s uterus.
- (e) Freezing excess embryos for potential replacement in a future cycle at the embryologist's discretion, depending on number and quality of Embryo’s

2. I/ We fully consent to these procedures and to the administration of such drugs and anaesthetics as may be necessary. We also consent to any other operative measures, which may be found to be necessary in the course of the treatment.

3. I/ We have been told of the risks of ultrasound directed follicle aspiration.

4. I /We have also had explanations and understood the reasons for using micromanipulation of human gametes to assist fertilisation using intracytoplasmic sperm injection (ICSI). I/We understand ICSI will only be performed after discussion and agreement between ourselves and the clinical team (additional costs apply).

5. I/we have been given the information sheet ‘Intracytoplasmic sperm injection’ and have had time to ask any questions relating to the potential risks associated with ICSI.

6. I /We understand that the chance of fertilisation and conception following IVF treatment

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using ICSI, in patients with a male factor is the same as when conventional IVF treatment is undertaken for patients who do not have a male factor.

7. The uncertainty of the outcome of the procedure has been fully explained to me/ us.

I/ We fully understand the risks of treatment including;

- there is no guarantee of success.
- it is not possible to guarantee that a follicle will develop in a given cycle and that occasionally cycles have to be abandoned before egg collection.
- there is a risk that spontaneous ovulation can happen prior to/ or during the egg collection.
- an egg is not always recovered from a follicle at the time of egg collection any eggs will be collected and fertilisation of any collected eggs will occur
- is a risk that the cycle will be abandoned before Embryo Transfer if there is failure of fertilization, abnormal fertilization or failure of the embryo to cleave (divide).
- a pregnancy may result from treatment.
- treatment may be abandoned at any time if there are problems in the laboratory or with the culture system

8. I/ We are aware that we are free to withdraw or vary the terms of this consent until the gametes and/ or embryos have been used in accordance with my/ our wishes. I am aware that this will have to be a written request.

9. If a clinical pregnancy does result from assisted conception treatment, I/ we understand there is an accepted risk of multiple pregnancy, an ectopic pregnancy or of a miscarriage. I/ We understand that as in natural conception, there is a small risk of fetal abnormality.

10. I/ We have been fully informed of all that is involved with the IVF technique and have been advised regarding the chances of success, the possibility of multiple pregnancy occurring and other possible complications of treatment by the doctor. I/ We have also received information relating to treatment by these techniques in order to assist us to become more fully aware of what is involved.

11. The Team at CREATE Fertility are constantly working on finding new and non-invasive methods to predict and improve egg and embryo quality and to make IVF treatment safer and more successful through research. We would like to study excess material including non-reproductive cells (granulosa cells & cumulus) and fluids from your follicles and culture media to understand more about egg maturity and markers for egg quality etc. This material is normally discarded after the completion of the cycle. Neither your eggs nor your cycle of assisted reproduction will be affected in any way. These projects will

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help in assisting all infertility patients in improving treatment options in the future. If you need more information or wish to speak to one of our doctors or embryologists, please let us know. We will assume that you give consent for us to use this material but if for any reason you do not give consent please tick here .

PHYSIOLOGICAL ICSI (pICSI)

I/We understand that ICSI and pICSI differ in terms of sperm selection methodology and cost and consent to the use of pICSI following discussion and agreement with the clinical team (there is an additional cost).

I/we have been given the relevant information sheet for the technique selected and have had time to ask any questions relating to the potential risks associated with pICSI

SECONDARY IVM

I/We understand we may be informed that (some of) my egg(s) retrieved after the egg collection procedure appear immature and therefore may not be suitable for in vitro fertilisation procedures. Following discussion and agreement (there is an additional cost) on the day I/we consent to the embryology team to apply the technique of 'In Vitro Maturation' to these eggs.

This involves the culture of the oocytes in a solution containing Follicle Stimulating Hormone (FSH) and hCG (Human Chorionic Gonadotrophin) for a period of 24 hours in order to enable the eggs to mature *in vitro*, followed by insemination with the ICSI technique (in which a single sperm is injected directly into each egg). I have received the information document on ICSI.

I understand that there is no guarantee that immature eggs will mature *in vitro*. I further understand that there is no guarantee that the oocytes will be viable after the process, or that fertilisation or pregnancy will occur.

CRYOPRESERVATION OF EMBRYOS CONSENT

1. I/ We understand that if any excess embryos result from our fertility treatments, they may be frozen if considered suitable and it is my/ our responsibility to confirm with CREATE whether embryos have been frozen or not (additional costs apply).

2. I/We further understand that:

(a) Storage of frozen embryos will be reviewed annually. Legally embryos can be stored for as long as indicated on your MT/WT form up to a maximum of 10 years Extending past this time is only allowed in certain circumstances depicted on the MT/WT form.

(b) I/ We (must both) give written consent before any embryos are thawed and replaced.

(c) No assurance can be given that any embryos will survive the freezing/storage/thawing process, nor will thawing necessarily result in the generation of viable embryos. I/ We, therefore, understand that the thawed embryos may not be suitable for subsequent transfer.

(d) No stored embryos will be removed from the custody of CREATE without written consent of myself/ ourselves (except in circumstances 4.(b) below).

(e) The intention to transfer thawed embryos in a specific menstrual cycle will be at the discretion of the embryology and medical staff of CREATE after consultation with me/ us.

(f) CREATE staff, management and its independent contractors shall not be deemed responsible for:

- (i) Any mechanical failure or accidental damage which might cause loss or damage to the embryos.
- (ii) Any damage to the embryos that might occur as a result of the freezing/storage/thawing process.

3. The disposition of our embryos in the event of my/ our death is in accordance with my/ our wishes recorded on our HFEA MS/MT and WS/WT consent forms as applicable.

4. I/We understand that I am/ we are:

(a) Completely responsible for contacting you once a year to confirm that we wish the embryos to remain in storage

(b) Jointly and severally responsible to pay an annual fee to cover administration and storage. Failure to pay the annual storage fee will result in the embryos being discarded prior to the end on the consented storage period.

(c) Jointly and severally responsible to inform CREATE of any change of address or any personal circumstances.

CREATE will make reasonable efforts to contact you at the latest address given, including writing to you by registered post and attempting to contact you by telephone. Failure to establish any contact will result in the embryos being discarded at the end of the consented storage period, as required under the Human Fertilisation and Embryology Act 1990.

I/we also understand that an export fee will be charged if I/we decide to transport my/our samples to another centre.

5. In the event that any contingency was to arise which is not covered by this agreement, then the decision as to how the embryos will be used will be made by two or more members of the clinical staff of CREATE.

I/ We have been given sufficient time to consider the contents of this document, and to make further enquiries before signing.

I/ We understand that counselling is available before, during and after treatment

I/ We have been offered the opportunity to receive counselling if I/ we so wish.

I/ We acknowledge that we will jointly and severally continue to be bound by the acknowledgements admissions and consents we have made and given in this letter in the event of my/ our subsequent change of personal circumstances, separation and/ or divorce.

I/ We fully understand that this consent is valid unless I/we change our circumstances or decide to revoke consent.

Patient Name

Patient Signature

Partner Name

Partner Signature

Date / /

Where the patient cannot sign in person:

Representative's declaration. I declare that the person named in section one of this form is present at the time of signing this form and I am signing it in accordance with his direction.

Representatives' name

Representatives' signature

Clinic Representative's Name

Clinic Representative's Signature

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