

Consent to IVF / ICSI

**About Patient One** (check your name and DoB carefully)

First name

Surname

Date of birth:



Patient I.D.

**About Patient Two** (check your name and DoB carefully)

First name

Surname

Date of birth:



Patient I.D.

Please select as applies to you:\*

Patient 2. Patient 1.

My/our personal circumstances **have not** changed since my/our last treatment (e.g. separation or divorce).

My/our personal circumstances **have changed** since my/our last treatment (e.g. separation or divorce). Please discuss these changes with your consultant.

**1 All Patients - Please tick all boxes that apply to you**

1.1 The name of the patient having the egg collection:\*

Patient 2. Patient 1.

1.2

I consent, as necessary, to the following in preparation for the egg collection to: \*

- Ultrasound scans
- Relevant blood tests
- Self-administering medication

I (the patient) consent to the removal of eggs from my ovaries with the aid of:

- Ultrasound scans
- Anesthetic and any other necessary drugs
- Laparoscopy

1.3 **I/We consent to the mixing of MY EGGS / PARTNER'S EGGS with the following: \***

Patient 2. Patient 1.

**MY sperm / PARTNER'S sperm**

**DONOR sperm**

Name of **SPERM DONOR** (only insert name if using sperm from a donor that you know)

I/We understand that only the egg(s) from one woman and sperm from one man will be used in any one treatment.

## **2 Patients using frozen sperm - Use of frozen sperm in treatment**

**Only for male partners who plan to use their own frozen sperm in their treatment or have frozen sperm as a backup**

I consent for my frozen sperm stored at the Lister Fertility Clinic, to be used in my partner's (the patient) treatment.

- This consent will validate the use of your sperm for your partner's treatment for this treatment cycle only.
- It is your responsibility to inform us if you want to withdraw your consent to use your sperm currently frozen or to cease storage.

## **3 Patients using donor sperm - Use of donor sperm in treatment**

**Only for couples and individuals who plan to use donor sperm in their treatment or have donor sperm as a backup**

I /We confirm that I/we understand the following:

- CMV Screening - National Guidelines suggest that: (i) the risk of CMV infection associated with donor assisted conception is not known (ii) propose screening of donors as the only way to exclude those who are infectious by this route, (iii) all donors are routinely screened for CMV, (iv) the use of CMV negative donors is always the preferred option to minimise the risk of new infection or reactivation in CMV negative recipients, (v) CMV negative sperm should always be sought, (vi) in situations where insufficient CMV-negative donors are available, CMV positive donors may be recruited and used on a case-by-case basis. At the Lister Fertility Clinic, because of the limited infection risk with assisted reproduction using egg/embryo/sperm donation, we believe that in certain circumstances, such as, known donation or no suitably available CMV negative donor, and with the explicit consent of both the recipient and their Lead Clinician that a CMV positive donor may be used for a CMV negative woman. This is at odds with the above mentioned National Guideline recommendation that CMV positive donors are limited to CMV positive recipients. Further relevant patient information is available the Clinic, and a consent form will need to be signed by a woman who is CMV negative and is choosing to use donor gametes from a CMV positive donor.
- Anyone donating gametes or embryos needs to be aware of the availability of genetic ancestry testing, and the implications that this might have for them. Online companies exist that allow individuals to submit their DNA profile to try and connect with others who are genetically related to them. This means that there is a possible lack of control over identity if an individual has a blood relation that had submitted their profile. An example might be if the sibling of a donor has uploaded their profile there might be the chance of a match with someone born from the donation if they have also entered into the scheme.
- An awareness of this is important for all donors, recipients and their families. The possibility of this early revealing of genetic heritage supports the early parental disclosure as endorsed by the HFEA. Issues surrounding this may be discussed in the non-medical implications counselling that all donors and recipients are required to have at the Lister. Further counselling sessions can be arranged if this is something that needs further individual exploration, or any medical questions can be directed to your Consultant.
- Through the use of counselling, the Centre encourages and prepare patients to be open with their children from an early age about how they were conceived. The Centre will give patients information about how counselling may allow them to explore the implications of treatment, in particular, how information may be shared with any resultant children. I/We have been offered implications counselling, and confirm that I/We have either had implications counselling at the Lister (or a previous clinic), or have declined it.
- Patients using donor sperm which were first stored in, or imported to, the UK before 19 October 2018, were screened under screening requirements that have since been updated. We have no concerns however as to the use of this sperm, which would have been quarantined or tested appropriately.

#### 4 All Patients - Risks of treatment

Patient 2. Patient 1.

4.1   I/We confirm that I/We understand the following: \*

- I/We understand that I/we need to have been screened for HIV, Hepatitis B and Hepatitis C within 3 months for first treatment (i.e. egg collection procedure for IVF procedure), and every 2 years thereafter for subsequent cycle for both the patient AND partner.
- I/We confirm that no travel has occurred for any consenting patient or partner to Ebola or ZIKA-affected areas during time periods outlined in current clinic information or that I/We have signed the Zika Awareness Patient Consent form.
- I/We have been made aware that the risks of IVF/ICSI treatment include, but are not limited to:
  - Multiple pregnancy and its associated increase risk of complications including, but not limited to, preterm labour, growth restriction, operative delivery, still birth, and maternal complications, such as, pre-eclampsia and diabetes.
  - Miscarriage / Ectopic Pregnancy.
  - Ovarian Hyperstimulation Syndrome (OHSS).
  - Cycle cancellation because of over- or under-response to hormone stimulation.
  - Uncommon surgical complications associated with egg collection: bleeding, infection, injury to bowel, bladder or blood vessels.
  - Pregnancy complications: studies have suggested an increased risk of some complications irrelevant of multiple pregnancy, such as, operative delivery, placenta praevia, placental abruption, pre-term labour, pre-eclampsia, and gestational diabetes. These risks also stem from the higher average age of those having treatment and the fact that the underlying cause of fertility may be the cause of the increased risk. There may be additional risk related to the treatment itself but it is difficult to assign the relative contribution of each.
  - Birth Defects: approx 2.5% of babies are born with birth defects. Babies following IVF/ICSI have been shown to have a small increase in such defects to approximately 3-3.5% with data not sufficient to show any risk of a specific defect. However, those with subfertility who subsequently conceive naturally also have an increased risk, so the risk due to treatment itself may be limited.
- I/We understand that in rare circumstances, in both IVF and ICSI cycles, no oocytes will fertilise normally or embryos may fertilise but develop abnormally. As a consequence, no embryos will be available for transfer/ freezing.
- I/We understand that in any IVF/ ICSI cycle there is a very low risk of technical problems, such as, equipment failure, which could result in harm or damage to my/our eggs/sperm/embryos.
- I understand that the Lister Fertility Clinic will take every care to uphold the safety of my/our sperm/gametes/embryos whilst they are in the laboratory/ in storage at the Clinic. I understand that the Lister Fertility Clinic has a duty to inform me of any technical problems that may have affected my care.

#### 5 All Patients - Consent to Intracytoplasmic Sperm Injection (ICSI)

Patient 2. Patient 1.

5.1   I/We confirm that I/we understand the information provided about ICSI; and understand the following: \*

- I/We understand what the procedure involves and am/are aware of the risks and limitations of this procedure.
- I/We understand that there is no guarantee that eggs that have undergone ICSI will fertilise, or that the transfer of any resulting embryos will guarantee a successful outcome.
- I/We understand that just as with spontaneous pregnancy, there is a risk of foetal malformation and that this risk may be increased following ICSI (see patient information).
- I/We am/are also aware of the possible genetic risk.
- I/We am/are aware of the tests available to detect foetal malformation during pregnancy.
- I/We understand that ICSI will incur an additional cost.

## 5 All Patients - Consent to Intracytoplasmic Sperm Injection (ICSI) continued

5.2 Tick one of the following (if you are being treated with a partner, it is very important that you discuss and agree if you wish to have ICSI):\*

Patient 2. Patient 1.

 

I/We consent to IVF with or without ICSI as recommended by the clinician at consultation or the embryologist on the day of the procedure depending on the quality of the sample.

 

I/We **DO NOT** consent to the use of ICSI in my/our treatment, even if it is recommended by medical and scientific staff. **I/we understand and accept that by refusing ICSI this may reduce the chance of fertilisation and embryos being created.**

## 6 All Patients - Consent to embryo transfer

Patient 2. Patient 1.

6.1   I/We confirm that I/we understand the information provided about embryo transfer; and understand the following: \*

- Embryos can be transferred from Day 2 onwards of development.
- The developmental potential of embryos often becomes more apparent between Day 3 and 5 and it is likely that if an embryo does not develop to the blastocyst stage it will not have the capacity to create a pregnancy.
- Natural selection will see the most viable embryos continue to grow to Day 5 whilst those of poor quality, and less likely to be genetically normal, will cease growing between Day 3-5.
- We will routinely culture embryos until we are able to select the best for transfer depending on how many you wish to transfer.
  - If you have **more embryos of good quality than you wish to transfer on Day 3** we will routinely recommend culturing to Day 5 to be able to better select the most viable
  - If on **Day 2 or 3 the best available are clearly identifiable** (i.e 1 or 2 only of good quality depending on how many you wish to transfer) we can transfer on this day with no benefit of waiting until Day 5 on pregnancy outcome.
- On some occasions, **based on previous history or personal choice (as discussed in advance with your consultant)** we can wait until Day 5 to transfer regardless of the number of embryos available, although there is a chance that no embryos will develop to Day 5, especially with poor quality embryos on Day 2-3. This option could potentially give useful information that would otherwise not be available on embryo quality, avoid unnecessary medication use, and the anxiety of the two week wait.
- I/We understand that blastocyst culture will incur an additional cost if there is an embryo suitable for transfer.

6.2 I/We consent to the following number of blastocysts or cleavage stage embryos to be transferred during this treatment cycle. The final decision will be made on the day of transfer with the embryo quality information available. (If you are being treated with a partner, it is very important that you discuss and agree the number to be transferred)  
\*

Patient 2. Patient 1.

 

**0 embryos** – Select for Freeze All Cycles

 

**Under 40: 1 or 2 embryos** (depending on the recommendations of medical and scientific staff, based on my medical history, age, and embryo quality).

 

**40 or over: 1, 2 or 3 embryos** (depending on the recommendations of medical and scientific staff, based on my medical history, age, and embryo quality). **PATIENT MUST BE 40 YEARS or OVER.**

The name of the patient having the embryo transferred: \*

## 6 All Patients - Consent to embryo transfer continued

Patient 2. Patient 1.

6.3   I/We confirm the following: \*

- I/We am aware that the replacement of more than one embryo may give rise to a multiple pregnancy.
- I/We am aware that a multiple pregnancy can be medically riskier to mother and babies, as well as having socio-economic implications. Increased risks to the mother include, but are not limited to, miscarriage, hypertension, pre-eclampsia, and gestational diabetes. Increased risks to babies include, but are not limited to, premature birth, perinatal mortality, neonatal care, respiratory distress, cerebral palsy, disability, delay in language acquisition, and congenital malformations.
- I/We have had a full discussion with the medical consultant with regards to the number of embryos to transfer, outlined above. I/We am aware of the increased risks to maternal health and the health of any babies should a multiple pregnancy ensue. I/We have been given information orally and in writing, and had the opportunity to ask questions.
- I/We have been informed of the small incidence of ectopic pregnancy and I/we have been made aware of the risk of miscarriage following treatment.
- I/We understand that an embryo transfer cannot take place until the Lister Fertility Clinic has received consent from both patient and partner.

## 7 All Patients - Embryo freezing

7.1 Tick one of the following (If you are being treated with a partner, it is very important that you discuss and agree):\*

Patient 2. Patient 1.

I/We consent to embryo freezing and storage

I/We do not consent to embryo freezing and storage. **In this instance, I/we understand that any embryos not used in my/our treatment will be allowed to perish.**

7.2 **If you have consented YES to freezing your embryos:**

I/We confirm that I/we understand the following:

- I/We understand that there is no guarantee that I/we will have embryos suitable for freezing.
- I/We am aware that freezing my/our embryos does not guarantee future fertility.
- I/We understand that I/we can request for my/our embryos to be thawed and that no assurance can be given that the embryos will survive or be suitable for transfer.
- I/We understand that any suitable embryos can only be stored for an initial period of ten years from the date of cryopreservation.
- I/We understand that after a period of ten years, there is a possibility of extending the storage period in ten-year increments ONLY if it is shown at any time within each extended storage period that the criteria for extended storage continue to be met (i.e. a medically certified risk of premature infertility). I/We understand I/we will need to complete the HFEA ES form to apply for storage extension and that there is a maximum storage period of 55 years.
- I/We understand that embryo freezing will incur a charge for the freezing process and an additional charge for the thawing and subsequent embryo replacement. I/We understand that after the first year of storage, I/We will be invoiced for storage on an annual basis.
- I/We understand that my/our stored embryos cannot be transferred from the Lister Fertility Clinic without my/our consent and that I/We need to submit the appropriate consent form to the clinic 28 days prior to the desired date of transfer.
- I/We understand that whilst the Lister Fertility Clinic will make every effort to keep embryos in optimal storage conditions during the storage period, the clinic will not accept any liability for mechanical breakdown of equipment, loss of power supply or other eventualities that are out of its control.

## 8 All Patients - Legal Parenthood

Patient 2. Patient 1.

8.1   I/We confirm that I/we understand the following: \*

- The birth mother will always be the legal parent of any child born.
- When donor sperm is used, and a couple is not married or in a civil partnership, under the Human Fertilisation and Embryology Act 2008, the partner can be the legal parent of any child born from the patient's treatment – as long as both the patient and the partner give their consent to this in writing. This consent is given by completing the HFEA WP and HFEA PP forms.
- When donor sperm is used, and a couple is married or in a civil partnership, and the patient is receiving treatment using embryos created outside the body (in vitro) using donor sperm with her own or donor eggs, and the partner wishes to be registered as the legal parent to any child born if they die before embryos (that were created before their death) are transferred to the patient, the partner should complete the HFEA PBR form.
- Where the birth mother is still legally married to or in a legal civil partnership with someone other than the person who she seeks treatment with, the situation can be more complex, and it is advised that you seek your own independent legal advice. This applies regardless of whether donor sperm or a partner's own sperm is being used in treatment.

## 9 All Patients - Declaration

Patient 2. Patient 1.

9.1   I/We confirm the following: \*

- I/We have received information on the social, ethical, and legal aspects, as well as the medical consequences of the procedures outlined above; and these have been explained in full.
- I/We have been given a suitable opportunity to take part in counselling about the implications of the proposed treatment.
- I/We have had the opportunity to discuss the risks associated with all of the treatment options consented to in this agreement.
- I/We understand that any suitable embryos can only be stored for an initial period of ten years from the date of cryopreservation.
- I/We have been made aware of the alternatives to the procedures outlined above.
- I/We have been given time to consider the content of this document and have been given the opportunity to make further enquires as I/we wish before signing.
- I/We am aware that both the patient and the partner can make changes to or withdraw their consent at any point until the time of sperm, egg or embryo transfer. If you would like to change or withdraw your consent, you should ask the clinic for a HFEA WC form.
- I/We understand that I/We are responsible for contacting the clinic if any of my/our contact details (phone numbers / address / e-mail) change.
- I/We declare that the information I/we have provided in writing is correct and complete.

Date



Date

