

# Patient Information

## New Storage Laws

Our regulating body, the Human Fertilisation & Embryology Authority (HFEA), have updated the storage regulations for gametes (eggs / sperm) and embryos:

- Patients are now able to store gametes/embryos for up to 55 years\* from the date of first storage provided consent is renewed every 10 years.
- Patients have the option to allow use of gametes/embryos with their partner in the event of their death or mental incapacitation.

*\*When embryos are created using donor gametes, the donor must have also consent to 55 years or the maximum period consented by the patient.*

### Storage Renewal

Your consent must be formally renewed every 10 years if you wish to keep your material in storage.

The renewal period begins 12 months prior to the expiry of your consent and ends 6 months afterwards (a total of 18 months).

The RFC will attempt to contact you at least 12 months before the expiry of each 10-year consent period to ask whether you wish to continue storage or not. When contacted, it is very important that you reply to us and let us know your wishes.

We will send the following Statutory Notices to you as appropriate:

**These are the HFEA 'Statutory Notices' which inform you of the requirements if you wish to renew consent to storage of gametes or embryos for treatment.**

1. RNG – Request to renew consent to storage of eggs or sperm within the renewal period.
2. RNE – Request to renew consent to storage of embryos within the renewal period.
3. NDG – Notification that eggs or sperm will be removed from storage and disposed of if the patient does not renew consent to storage before the end of the renewal period.
4. NDE – Notification that embryo(s) may be removed from storage and disposed of if patients do not renew their consent to storage before the end of the renewal period.
5. NWC – Notification to each person whose eggs or sperm were used to create embryo(s) that consent to storage has been withdrawn.

If at the end of the renewal period, you have not replied and provided written renewed consent, the law states that this will be taken as proof of lack of consent and your gametes (sperm or eggs) will be removed from storage and disposed of.

By law, embryo(s) may continue to be stored for a further period of 6 months after the end of this 18 month renewal period after which, they must be removed from storage and allowed to perish. However, it is crucial to note that you will no longer be able to renew your consent to storage or use your embryo(s) in this time (i.e after the 18 month renewal period).

The RFC will contact you at each successive 10-year period. You will be required to follow the renewal process at every successive 10-year period until a maximum storage period of 55 years has been reached at which time the gametes or embryos must be removed from storage and disposed of.

### **Consenting to storage for less than 10 years**

You can choose to store your gametes or embryos for a period less than 10 years. You should consider carefully your reasons for consenting to a short period and be aware of the requirements of renewal of consent (renewal period) and the consequences if consent is not renewed in the renewal period (i.e. that consent is taken to be withdrawn). Importantly, there is no grace period when extending consent to storage for periods less than 10 years. Material will be removed from storage the day the consent expires. This could happen if you have not contacted the clinic and extended your consent to storage or we have been unable to get in contact with you.

### **Making the decision to renew my consent**

The decision whether to renew your consent and keep sperm, eggs or embryos in storage can be a challenging one. It is vital that you think carefully about this decision every time your consent is renewed or extended and consider whether it is likely you would use these in your own treatment or the treatment of your partner, including treatment with a surrogate in the future. It is also important to consider whether you may wish to donate these for the treatment of others in the future or for training.

It is important to carefully consider and discuss with your partner, if appropriate, the implications of future treatment for yourself and others including factors such as age, general health and the risks of such a pregnancy in the future as well as the implications for any future children.

Although the law permits a maximum storage period of 55 years few women would seek to carry a pregnancy beyond the age of 50 and this may not be possible.

Other examples of things you may wish to consider and discuss when making such a decision

- The chances of a livebirth using the material in the future
- The costs associated with use of this material in the future
- What your wishes would be if you became sick or died
- The implications of using gametes or embryos after either partner dies
- The welfare of any children born in the future
- The implications for you and any children if material is donated and used many years in the future

## **Counselling**

This is a complex area and we offer you the opportunity to receive counselling about the implications of renewing your consent with our fertility counselling service. This can be really useful when balancing all the complicated implications around storage and potential use into the future or how you feel about allowing material to perish. If you would like to have counselling, you can arrange this independently or through the RFC.

## **Change of contact details**

The management of your stored eggs, sperm & embryos by the RFC is in partnership with you. Whilst we have certain legal obligations and duties, it is also vital that you take ownership and responsibility for this precious resource. It is essential that you keep us informed of any changes to your contact details, GP or to your relationship status. We sometimes find it difficult to contact patients after long periods of time particularly if they have moved house or country. If we cannot contact you or, you do not respond to our attempts to obtain consent when your storage period is due to expire, the law now states that this will be taken as proof of lack of consent.

## **Change of Circumstances**

It is important that you make the RFC aware of any changes in your circumstances which may affect your consent decision (for example, if you have separated from your partner or have a new partner). This is important so that your wishes can be carried out in the unlikely event of death or mental incapacity. We also ask you to provide contact details for your next of kin and it is important that you make us aware of any changes to these details also. The RFC complies with all relevant confidentiality (including section 33 of the HFE Act 1990 (as amended)).

## **Storage Long Term**

Eggs, Sperm and Embryos are stored in liquid nitrogen at  $-196^{\circ}\text{C}$  and do not deteriorate with time. There is a theoretical risk of cross-contamination between samples, however, the RFC now screens all patients before treatment to minimise this risk.

In the RFC, the chances of achieving a pregnancy and live birth from a frozen embryo are similar to those when using a fresh embryo. A small number of embryos do not survive the freeze and thaw process.

Eggs are more fragile than embryos and the chances of achieving a pregnancy and live birth from a frozen egg are less than those with a frozen embryo.

Sperm quality varies. At the time of sperm storage, you will have been informed of the quality of the sperm stored and the type of treatment it would be suitable for.

Please be aware that, although deterioration does not occur over time, the RFC cannot accept any responsibility for accidental damage to any frozen stored embryo(s) due to circumstances outside its control, including, but not limited to: loss, fire, damage, contamination, equipment failure.

## **Consent to treatment**

You will be asked to provide your consent to the use of your sperm or eggs in treatment (IVF or ICSI). If you have a partner, you may also wish to consider storing your sperm for your partner's future treatment with IUI.

## **Consent for use of your gametes or embryos in training or research**

The new consents allow you to consent for other uses of your gametes or embryos in the future, including for use in someone else's treatment, training, or research.

Training activities or research can only be carried out in accordance with relevant standard or research licence conditions. At present the RFC does not hold a research license or have an agreement with a research centre. The RFC cannot therefore accept gametes or embryos for research. Please be aware that if you consent to donate your gametes or embryos and they have already been used in training or transferred to training, they cannot then be used in treatment should your circumstances change.

When consenting to training, you can specify any period of storage of gametes for use in training up to 55 years and you will not need to periodically renew consent for training. For embryos, you can specify any period of storage of embryos for use in training up to 10 years from the date that you give consent.

## **Posthumous (after death) use of gametes and embryos**

Gametes or embryos can only be used posthumously (after death) by a partner if you have provided written consent to posthumous storage and use, and named your partner on your consent form.

If at the time of storage, you do not have a partner but you later meet a partner and want them to be able to use your gametes or embryos in the event of your death, you must inform the RFC and update your consent form(s) as soon as possible. Unless your partner is named on your consent form(s), they would not be legally able to use your gametes or embryos even if you have provided effective consent to posthumous use.

If treatment after death would involve a surrogate, then additional consent forms and screening must be completed to allow surrogacy treatment to take place. You must be screened in line with requirements for gamete donors. If this is something that you wish to consider, you should contact the RFC for more information on screening and associated costs.

## **Storage and use of gametes or embryos after death**

The new consent forms allow you to state what you wish to happen in the event of your death.

They also allow you to consent to being registered as the legal parent of any child born as a result of your partner's treatment, if treatment occurs after your death.

You can consent to use and storage of your gametes or embryos for up to 10 years in these circumstances. If you consent for a period less than 10 years, you will not be able to benefit from the full amount of time (10 years) permitted in law.

It is unlawful to store gametes for longer than 10 years from the date of death.

Embryos can however be stored for a further six months after 10 years from the date of death.

If gametes in storage are used to create embryos after death, those embryos can only be stored and used for 10 years from the date of death, not from the date of first storage of the embryos. Embryo storage can continue lawfully for a further six months after the end of the 10-year period (or less if the maximum period of 55 years from date of first storage is reached).

The consent of both patients (gamete providers) is needed to store embryos. If the living patient withdraws their consent to storage at any point in the posthumous 10-year storage period, embryos must be removed from storage and disposed of.

The RFC will endeavour to contact any named partner 12 months before this 10-year storage period ends to inform them that at the end of this 10-year period any unused gametes or embryos will be removed from storage and disposed of.

### **Use of gametes or embryos in the event of mental incapacity**

The new consent forms allow you to state what you wish to happen in the event of mental incapacity.

Your gametes or embryos can only be used by your partner if you have provided written consent to their storage and use in these circumstances, and your partner is named on your consent form.

If you do not have a partner when your gametes or embryos are placed in storage and you later meet a partner who you want to be able to use their gametes or embryos in the event of mental incapacity, you must inform the RFC and update your consent form(s) as soon as possible. Partners of patients who are not named on the patient's consent form(s) are not able to use gametes or embryos even if the patient has provided effective consent to use in the event of their mental incapacity.

If treatment after mental incapacity would involve a surrogate, then additional consent forms and screening must be completed to allow surrogacy treatment to take place. You must be screened in line with requirements for gamete donors. If this is something that you wish to consider, you should contact the RFC for more information on screening and associated costs.

It is unlawful to store a patient's gametes for any longer than 10 years from the date on which they lose mental capacity, as certified by a medical practitioner, unless the patient has regained mental capacity and renewed their consent to a longer storage period in the intervening time. It is not unlawful to store embryos for a further six months after the 10 years from the date on which they lose mental capacity.

The storage period after death or mental incapacity must not exceed the maximum storage period of 55 years from the date of first storage.

If gametes in storage are used to create embryos after loss of capacity, those embryos can only be stored and used for 10 years from the date of the certification of the gamete provider's loss of capacity, not from the date of first storage of the embryos.



At the end of the 10-year period (or less if the maximum period of 55 years from date of first storage is reached) the gametes must be removed from storage and disposed of. In the case of embryos, however, they can be stored for a further six months after the end of the 10-year period (or less if the maximum period of 55 years from date of first storage is reached) from the date of certification of loss of capacity unless the RFC receives written notification of withdrawal of consent to storage of the embryo from the other gamete provider.

Consent of both gamete providers is needed to store embryos. If the other gamete provider withdraws their consent to storage at any point in the 10-year storage period, embryos must be removed from storage and disposed of.

The RFC will endeavour to contact any named partner 12 months before this 10-year storage period ends to inform them that at the end of this 10-year period any unused gametes or embryos will be removed from storage and disposed of.

If a patient regains mental capacity within 10 years of the date on which they were certified as having lost capacity, they should inform the RFC so that they can discuss whether they wish to renew their consent to the storage of their gametes or embryos. If the RFC is not made aware that the patient has regained capacity, then they will be required to remove the samples from storage 10 years from the date on which the patient was certified as lacking capacity. If the patient decides to renew their consent to storage, the maximum period of storage cannot exceed 55 years.

### **Withdrawal of Consent**

At any point during storage you may decide to withdraw your consent to storage. If you withdraw your consent to storage for treatment purposes, we may ask you to consider whether you would like to consider giving consent to the use of your gametes or embryos for someone else's treatment (if appropriate), in training or whether they would like them to be removed from storage and disposed of. You will then be required to complete the relevant withdrawal of consent form. If you give consent for storage for use in training then this also means it is possible that gametes or embryos may be used in training even after death or mental incapacity. If you do not wish for this to happen, you should not give consent to storage for use in training.

### **Withdrawal of consent to embryo storage or use by one partner**

You can withdraw consent to the storage of embryos created with your own gametes and a partner. If this happens, the RFC will take several actions:

- Your partner/ex-partner will be notified by the RFC of your wishes.
- You will enter what is called a 12-month cooling off period where embryos are kept in storage but cannot be used and both parties will be offered counselling (together or separate).
- During this period the embryos will not be able to be used unless with consent withdrawal is removed by the person initiating it.
- After 12 months if you still wish to withdraw consent, the embryos will be discarded even if the other partner does not wish to do so.
- If you withdraw consent to use embryos, they can remain in storage as long as you wish without being used.