

Guidance for clinics where consent to storage expires before 1 July 2022

This is [update 1 on the new amendments](#) to the Human Fertilisation and Embryology Act 1990 introduced by the [Health and Care Act 2022](#) that will come into force on 1 July 2022.

Update focus: Actions to be taken where consent to storage expires before 1 July 2022

Date updated: May 2022

Background

Under the Human Fertilisation and Embryology Act 1990 ('the 1990 Act') gametes and embryos can only be stored with the consent of the gamete provider or providers. Clinics must obtain written informed consent to storage of gametes or embryos and, subject to the exception described below, must ensure that they are only kept in storage in accordance with that consent.

Statutory Storage Period

It is a condition of every clinic's licence that gametes or embryos are not kept in storage for longer than the statutory storage period, and this fundamental principle will remain the case even once the amendments to the 1990 Act come into effect.

Prior to 1 July 2022 that period is 10 years, but **from 1 July 2022 new statutory storage periods will be introduced which will vary depending on the purposes for which patients have consented to their gametes or embryos being stored.**

Transitional period

The [Health and Care Act 2022](#) introduces a transitional period which will run from 1 July 2022 – 30 June 2024. During this period, there are a number of actions that clinics will need to take in particular in relation to gametes or embryos already in storage (i.e. in storage before 1 July 2022) where consent expires between 1 July 2022 – 30 June 2024.

Changes to storage where consent expires before 1 July 2022

Currently, it is a requirement under the 1990 Act that if gametes or embryos are in storage at the end of the 10-year statutory storage period, they should be removed from storage and allowed to perish (unless the requirements for extended storage under the relevant Regulations have been fulfilled). This means that where consent expires prior to 1 July 2022, clinics would ordinarily be required to remove them from storage and dispose of them.

However, the Transitional Provisions of the Health and Care Act 2022 (which will come into effect on 1 July 2022), provide that where consent expires before this date, ongoing storage of gametes or embryos at any time up to 30 June 2024 (i.e. the end of the Transitional Period) will not be unlawful merely because there is no effective consent to storage.

In other words, ongoing storage will not be unlawful in the period from 1 July 2022 to 30 June 2024 merely because consent expired before 1 July 2022.

Actions for clinics to consider

In light of this, clinics may consider it reasonable to continue storing material in certain cases, notwithstanding that consent may have expired. When the new provisions come into effect on 1 July 2022, clinics will be required to take the necessary steps to contact gamete providers to seek their written consent to storage. Such requests must be made in writing before 1 July 2023. Further detailed guidance will be provided about this in due course.

Whilst clinics may consider that it is reasonable, given the imminent change in the law, to continue storing material even after the gamete provider's consent has expired, **every precaution must be taken to ensure that the material is not used in treatment until effective consent to storage has been obtained.** In simple terms, if you continue to store the material once consent has expired you must not use the material until effective consent to storage is in place.

Clinics are reminded that under section 3 and 4 the 1990 Act, they are prohibited from using gametes or embryos in treatment except 'in pursuance of a licence'. The Transitional Provisions, as described above, do not change this fundamental position and so clinics that use any gametes or embryos in treatment when there is no effective consent to storage will not be using them 'in pursuance of their licence' and may be committing an offence under section 41 of the 1990 Act. In other words, the Transitional Provisions effectively enable a grace period in which clinics can obtain effective consent for ongoing storage, but they do not authorise use of the gametes or embryos concerned unless and until that consent is obtained.

Clinics will be expected to take steps to ensure that as little material is kept in storage without effective consent as is possible. In particular, clinics should be mindful of scenarios in which gametes or embryos are already beyond their statutory storage period consented to and so should have been destroyed, especially in cases where they have gone significantly beyond the permitted storage period such that the likelihood of obtaining effective consent is limited.

Below are actions for clinics to consider in cases where consent expires before 1 July 2022 and the gamete provider or person to be treated is prematurely infertile or likely to become so, and in cases where consent expires before 1 July 2022 and storage cannot be extended under the 2009 Regulations:

Cases where consent expires before 1 July 2022 and the gamete provider or person to be treated is prematurely infertile or likely to become so.

1. Where consent to storage of gametes or embryos expires before 1 July 2022, and where the gamete provider, or the person to be treated, is or is likely to become prematurely infertile, steps should be taken to extend storage under the relevant provisions of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ('the 2009 Regulations'). These steps should be taken **before** consent expires.
2. Both requirements of the 2009 Regulations must be satisfied in order to extend storage. These are (i) the requirement for the gamete provider to give written consent to storage for treatment purposes for longer than 10 years, and (ii) for a registered medical practitioner, on any day within the 'relevant period, to have given a written opinion that the gamete provider, or person to be treated, is or is likely to become prematurely infertile.

3. It is important that clinics consult the 2009 Regulations for the meaning of 'relevant period'. The 2009 Regulations were amended in 2020 by The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 ('the Coronavirus Regulations') and 'relevant period' is defined in slightly different terms depending on the provisions of the 2009 Regulations that are applicable. Guidance on extending storage under the 2009 Regulations and how the 'relevant period is defined' can be found in Guidance Note 17 in the [HFEA Code of Practice](#).
4. The change in the law from 1 July 2022 will require clinics to request gamete providers to renew consent to storage where the gametes or embryos are stored for the gamete provider's own treatment or for the treatment of the gamete provider together with another person. Such renewal of consent will be required every 10 years. Where storage is extended under the 2009 Regulations before 1 July 2022, this 10 year period will not begin until the date of expiry of the extended storage period under the 2009 Regulations.

Important considerations when contacting patients and donors

5. Before contacting patients and donors in particular, clinics should consult Guidance Note 30 in the [HFEA Code of Practice](#) and in addition, consider taking steps to mitigate the risk of breaching patient and donor confidentiality and section 33A of the 1990 Act. This is particularly important where clinics have not been in regular contact with the patient or donor.
6. Appropriate steps might include for example only using the patient or donor's preferred method of contact; making contact by telephone before sending email or correspondence by post; using email instead of sending correspondence by post; marking correspondence as 'confidential' and 'to be opened by addressee only' and ensuring correspondence does not contain any information which would identify it as having been sent by a fertility clinic.
7. If you have made reasonable attempts but cannot contact patients and donors, or where they do not wish to continue storing, clinics should remove their gametes or embryos from storage where consent has already expired or remove it from storage as soon as their consent expires or they withdraw their consent. This is the case whether the consent expires during or after the transition period.

Cases where consent expires before 1 July 2022 and storage cannot be extended under the 2009 Regulations

8. It should not be assumed that every patient or donor whose consent will lapse before 1 July 2022 will want to continue storing their gametes or embryos or wish to benefit from the 55-year statutory storage period that will be introduced from 1 July 2022. Where a patient or donor's consent expires before 1 July 2022, clinics should consider contacting them to advise of the imminent change to the law.
9. Where clinics contact patients and donors, they should inform them of the imminent changes to the statutory storage period and establish whether, in light of this, they wish to continue storing their material so that, after 1 July 2022, they can give further consent to storage. When contacting patients and donors, clinics should have regard to the paragraphs 5 to 7 above and Guidance Note 30 on Confidentiality and Privacy in the [HFEA Code of Practice](#).
10. Where patients or donors do not want their gametes or embryos to remain in storage, clinics should follow their usual procedures and remove the material from storage. If patients and donors wish to continue storing in these circumstances and it is not possible to extend storage under the 2009

Regulations, it is reasonable, given the imminent change in the law, for clinics to continue storing albeit that strictly this will be unlawful until 1 July 2022.

11. The HFEA will take a proportionate approach where clinics continue storing in these circumstances, mindful of the length of time for which the relevant gametes or embryos have been stored unlawfully as at 1 July 2022.
12. It is important that clinics make patients and donors aware that after 1 July 2022 and before 1 July 2024, they will be required to give written consent to storage, and that treatment using the patient or donor's stored gametes, or embryos will not be lawful until they have provided a further consent (which can only take place on or after 1 July 2022 when the new statutory storage period comes into effect). Clinics should advise patients that if they fail to provide a consent within the period 1 July 2022 to 30 June 2024, their gametes or embryos will be removed from storage.

We will be issuing further guidance for clinics about the new amendments at the end of May/early June that will set out the steps clinics must take from 1 July 2022. This will include the use of new and amended consent forms, revised General Directions and Licence Conditions, along with a detailed Clinic Guide on storage to help clinics understand the new statutory storage periods and comply with the new legal requirements.

If you have any questions about cases where consent expires before 1 July 2022 you should contact your inspector.