

FAQ Coronavirus Regulations

Annex II

1. Under the new Coronavirus Regulations, who will be eligible to extend their storage to 12 years?

Patients whose gametes or embryos are in storage at a licensed treatment, storage or research clinic will be able to extend their storage for 12 years provided:

- their gametes or embryos are in storage on 1 July 2020, the date the Regulations come into force, and
- they consent in writing to their gametes or embryos being stored for at least 12 years. This consent can be provided before, on or after 1 July 2020.

Example 1.1:

In July 2011, a patient consented to storage for 10 years, and the statutory storage period is therefore due to expire in July 2021. However, the patient satisfies the requirements of the Coronavirus Regulations, and thus the statutory storage period can be extended to 12 years. Their storage period will therefore expire in July 2023. If, as at 1 July 2020, more than 12 years have passed since gametes or embryos were first placed in storage and the storage period has not been extended under the 2009 Regulations, the gametes or embryos concerned will not be eligible for an extension under the Coronavirus Regulations. This is because the Coronavirus Regulations only provide for an extension of an additional two years **up to 12 years**.

2. What consent form should be used for patients who wish to consent to storage for 12 years?

We have produced a new consent form (CVS form) which patients can use to provide their written consent to store their gametes or embryos for 12 years. Note that the 12-year period is calculated from the date the gametes and embryos were placed into storage.

If patients meet the medical criteria for premature infertility and have previously consented to storing their gametes or embryos for at least 12 years, they will not need to sign the CVS form.

3. How do the Coronavirus Regulations impact on patients who are prematurely infertile and wish to store their gametes or embryos for up to 55 years?

The Coronavirus Regulations amend the meaning of 'relevant period' to reflect the fact that the Coronavirus Regulations provide for a one-off extension from 10 years to 12 years. The effect of this is that patients who are prematurely infertile or who are likely to become prematurely infertile will have an extra two years within which to obtain a written medical opinion to that effect and to extend storage under the 2009 Regulations or further extend storage under those Regulations where gametes or embryos were being stored subject to an extended storage period.

Example 3.1

In July 2011, a couple had embryos created and consented to storage of their embryos for 10 years. The statutory storage period is therefore due to expire in July 2021.

The patients satisfy the requirements under Regulation 3 of the Coronavirus Regulations and the storage period is extended to 12 years. Storage will therefore expire in July 2023.

The egg provider is however prematurely infertile.

A written opinion on premature infertility is provided in January 2023 which is within 12 years of the date the embryo was first placed in storage, i.e. within the 'relevant period' as defined by Regulation 3(6)(a) of the 2009 Regulations (as amended by the 2020 Regulations). As such, the storage period can be extended by a further ten years to January 2033 (under Regulation 3(2) of the 2009 Regulations).

4. How do the Coronavirus Regulations apply in the case of patients who have previously satisfied the requirements of the 2009 Regulations and whose gametes or embryos are currently in storage for an extended period i.e. beyond ten years?

Provided these patients satisfy the relevant provisions of the 2009 Regulations (as amended by the Coronavirus Regulations) their storage period will end at 12 years, instead of 10 years, after the date of the most recent written medical opinion given. Provided that these patients have previously given consent to storage for at least 12 years, they will not need to complete the new CVS form.

Example 4.1

Patients placed embryos in storage in January 2002 and consented to storage for 10 years. The statutory storage period expired in January 2012. A written medical opinion was given in September 2010 (before January 2012) and the patients consented to a further 10 years' storage. The 10-year extended storage period under the 2009 Regulations is due to expire in September 2020.

For a reason relating to the Coronavirus, the couple is unable to obtain a further written opinion within this 10-year extended storage period i.e. before September 2020.

Under Regulation 3A of the 2009 Regulations (as amended by the Coronavirus Regulations), the couple is entitled to extend the 10-year storage period to 12 years, however in this case, the 12 years is calculated from the date of the most recent previous medical opinion given in September 2010.

Their 12-year storage period will therefore expire in September 2022.

5. What about patients whose storage expired between 23 March 2020, when the HFEA issued General Direction 0014 (version 1) requiring clinics to cease treatment and 1 July 2020, when the new Coronavirus Regulations came into force?

Patients whose gametes or embryos are in storage at a licenced treatment, storage or research centre on 1 July 2020, the date the Regulations came into force, will be able to extend storage to 12 years from the date their gametes or embryos were first stored, provided they satisfy the relevant requirements set out in the Coronavirus Regulations. The Regulations do not stipulate that the gametes or embryos must be lawfully in storage in order to be eligible for the extension.

6. For donor gametes or embryos created with donor eggs or sperm, do the donors have to be contacted if the patients wish to extend to 12 years?

If a donor has only consented to storage for 10 years, storage can only be extended to 12 years under the Coronavirus Regulations if the donor consents to this using the new CVS Form.

When the donor(s) has previously consented to storage for at least 12 years, storage can be extended to 12 years without the need for the donor(s) to complete the CVS form.

7. Do clinics need to contact patients to tell them about the new Regulation?

Clinics should take all reasonable steps to contact patients whose gametes or embryos are in storage on 1 July 2020 to inform them of the Coronavirus Regulations and offer them the option to consent to extend their storage to 12 years, as well as an offer of counselling. To extend to 12 years patients will need to complete the new CVS consent form.

8. Will patients who store their gametes or embryos for the first time after 1 July 2020 i.e. the date that the Coronavirus Regulations come into force, be eligible to store for 12 years?

No, the Coronavirus Regulations only apply to patients whose samples were in storage on 1 July 2020, the date the regulations come into force. The Coronavirus Regulations will not apply to any gametes or embryos which are put into storage after this date.

9. What will happen to samples that are about to reach the end of the 10-year storage limits, where centers are unable to contact patients to get their consent to store for 12 years (for instance because of loss of contact)?

As patients have to consent to storage for 12 years using the new CVS consent form, if a patient cannot be contacted and therefore cannot provide written consent to extend to 12 years, the samples will need to be discarded when the original storage period that the patient consented to ends.

10. Can samples that have been donated to research be stored for 12 years?

Material that has been donated to research can also benefit from 12 years storage, but only if the gamete provider(s) give their consent and completes the CVS form.