

EXPLANATORY MEMORANDUM TO

THE HUMAN FERTILISATION AND EMBRYOLOGY (STATUTORY STORAGE PERIOD FOR EMBRYOS AND GAMETES) (CORONAVIRUS) REGULATIONS 2020

2020 No. 566

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

- 2.1 The Human Fertilisation and Embryology Act 1990 (“the 1990 Act”) and the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 (S.I. 2009/1582) (“the 2009 Storage Regulations”) set out the statutory scheme for the storage by fertility clinics of gametes (sperm and eggs) and embryos intended for future use in fertility treatment or research. The statutory time limit is ten years. Extensions to this can be made where a written opinion from a registered medical practitioner is given that a relevant person, as specified in the 2009 Storage Regulations, is, or is likely to become, prematurely infertile. Where this evidence is provided, the limit can be extended in ten year intervals, up to a maximum of fifty five years.
- 2.2 This instrument extends the statutory storage period for gametes and embryos, as set out in section 14(3) and (4) of the 1990 Act, in certain circumstances, from ten years to twelve years. It also amends the 2009 Storage Regulations to enable persons who have not been able, for a reason relating to coronavirus, to obtain a further written opinion from a registered medical practitioner within the time specified in the 2009 Storage Regulations, to, in certain circumstances, benefit from a two year extension to the statutory storage period.
- 2.3 This instrument is made in response to the global COVID-19 pandemic which has led to special measures being taken across the health sector, for example, the cancellation of non-urgent treatments in the NHS, including fertility treatments.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

- 3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

- 4.1 This instrument extends to the United Kingdom.
- 4.2 This instrument applies to the United Kingdom.

5. European Convention on Human Rights

5.1 Lord Bethell, the Parliamentary Under-Secretary of State for Innovation has made the following statement regarding Human Rights:

“In my view the provisions of the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 are compatible with the Convention rights.”.

6. Legislative Context

- 6.1 The 1990 Act, as amended by the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”), sets the statutory storage period for gametes and embryos at a maximum of ten years (section 14(3) and (4)). However, the 1990 Act includes a power, in section 14(5), enabling the Secretary of State to make regulations providing that the ten year period in section 14(3) and (4) may have effect as if there were substituted a shorter or, in specified circumstances, a longer period. This power was previously exercised to make the 2009 Storage Regulations, as amended by S.I. 2009/2581.
- 6.2 The 2009 Storage Regulations enable the statutory storage period to be extended at any point within the initial ten year period for a further ten years if one of the gamete providers, the woman who is to be treated with the embryo, or the person to whom the gamete or embryo has been allocated, is prematurely infertile or is likely to become prematurely infertile, for example, a person whose ovarian function has been affected by chemotherapy or radiotherapy. This must be evidenced by way of a written opinion from a registered medical practitioner.
- 6.3 The statutory storage period may then be extended for subsequent ten year periods, until a maximum storage period of 55 years is reached, provided that the premature infertility criteria are demonstrated at any time within each ten year period.
- 6.4 These Regulations are made under powers in sections 14(5) and 45 of the 1990 Act. The power in section 14(5), is subject to the negative procedure (see: section 45(5) of the 1990 Act). These Regulations extends the statutory storage period to twelve years where the relevant gametes or embryos are, on 1 July 2020, being stored on a premises which is licensed to carry out storage, treatment or research activities under Schedule 2 to the 1990 Act and the relevant persons, as specified in the regulations, have provided consent to storage for at least twelve years.
- 6.5 This will enable persons who have gametes or embryos stored in licensed premises on 1 July 2020 (whether for use in treatment services or for a project of research) to, if they provide the necessary consent, extend the statutory storage period for their gametes or embryos to twelve years from the date they were first placed in storage. This includes persons who have gametes or embryos in storage on 1 July 2020 which, on that date, have been stored past the ten year statutory storage period. These Regulations only apply in relation to gametes or embryos stored on 1 July 2020 and so they will not affect the status of any past storage.
- 6.6 These Regulations also amend the 2009 Storage Regulations so that specified persons who have previously extended the statutory storage period for gametes or embryos under the 2009 Storage Regulations may also, in certain circumstances, benefit from a two year extension to the statutory storage period. An extension will be available where a previous written opinion has been given by a registered medical practitioner and the relevant persons, as specified in these Regulations, are unable, for a reason relating to coronavirus, to obtain a further written opinion within ten years from the

date of the most recent previous written opinion. The extended storage period will begin when the gamete or embryo was first placed in storage and end twelve years, as opposed to ten years, after the date of the most recent previous written opinion.

- 6.7 The effect of this amendment is that the persons specified will have an additional two years in which to obtain a further written opinion from a registered medical practitioner (and may thereafter extend the statutory storage period by further ten years under regulations 3 or 4 of the 2009 Storage Regulations).

7. Policy background

What is being done and why?

- 7.1 There are a number of reasons why people undergo fertility treatment. Depending on the circumstances of each person undergoing fertility treatment, gametes or embryos that are not used immediately to have a child can be frozen for the purposes of artificial insemination or IVF treatment.
- 7.2 Increasingly people have been choosing to freeze and store their gametes. This may be because:
- they are not ready to have a family but want to preserve their fertility so that they can start a family later in life; or
 - they are having cancer treatment that may affect their fertility and wish to keep options open to start a family, or;
 - they may be planning on transitioning or having gender reassignment surgery but intend to start a family later.
- 7.3 The broader health sector response to the COVID-19 pandemic has led to special measures being taken, for example, as noted above, the cancellation of non-urgent treatments in the NHS, including fertility treatments. Professional bodies in the fertility sector recommended that no new treatments be started across the whole sector and the regulator, the Human Fertilisation and Embryology Authority (“HFEA”), issued General Direction 0014 to all NHS and private clinics which had the effect of suspending treatment services (with certain limited exceptions), effective from 23 March 2020. The direction was varied on 11 May 2020, but clinics still need to meet robust criteria assessed by the HFEA that they can provide safe treatment. As a result, there will be some clinics that can re-open sooner than others.
- 7.4 The special measures have meant that all those with gametes and/or embryos in storage were not able to access them for the period of the suspension and for many this will continue while clinics put in place measures to ensure that any treatment carried out is safe during the pandemic. Some may pass the current ten year storage limit and all others will draw closer to the end of their storage limit, which may limit their future treatment options. Some persons who may be able to extend the storage limits by providing evidence in relation to premature infertility may not be able to obtain the necessary medical opinions to help secure an extension.
- 7.5 The Government has received representations from the HFEA and patient stakeholder groups that the suspension of non-medical services, including fertility treatments, will have a particularly adverse effect on those with gametes or embryos in storage where the statutory storage period is coming to an end. In order to help persons with gametes and embryos in storage during the time the special measures taken in response to COVID-19 are in place, the Government has decided to introduce regulations to offer a two year extension of the statutory storage limit, increasing the statutory storage limit to twelve years. This will ensure that such persons have the opportunity to utilise

their stored material when services resume without undue pressure to make decisions. Representations have also been made for the regulations to cover material that has been donated for research purposes. The regulations therefore also cover gametes and embryos donated for research so that research projects are not negatively impacted by the pandemic.

- 7.6 Part 2 of these Regulations extends the statutory storage limit for gametes and embryos from ten years to twelve years. Regulation 3 increases the limit in respect of embryos while regulation 4 makes an equivalent extension in respect of gametes. The extension applies where, on 1 July 2020, the gametes or embryos are being stored in a licensed premises. It is a requirement of the 1990 Act that gametes or embryos (the creation of which was brought about in vitro) must not be kept in storage unless there is an effective consent to that storage and the gametes or embryos are stored in accordance with that consent (see: paragraph 8 of Schedule 3). In light of this, the extended statutory storage period will only apply where, in respect of embryos, the two people whose gametes were used to bring about the creation of the embryo have consented, whether before or after 1 July 2020, to the embryo being stored for at least twelve years. Equally, in respect of gametes, the person who provided the gamete must consent, whether before or after 1 July 2020, to the gamete being stored for at least twelve years.
- 7.7 These Regulations expressly provide that consent may be provided before 1 July 2020. While in most cases, the gamete provider, or the person whose gametes are used to create an embryo, will consent to storage for the current statutory storage period and therefore an additional consent will be required if such persons wish to extend the statutory storage period for their embryos or gametes, there are cases where written consent for storage beyond the current statutory storage period may have been provided. For example, consent to the posthumous use of gametes or embryos for the treatment of a partner.
- 7.8 The rationale for the extension under Part 2 of these Regulations is to ensure that persons who may have already been impacted by the special measures taken in response to COVID-19 have more time to obtain fertility treatment and equally to help ensure that those who may seek fertility treatment in the future do not lose out because of any resulting delays to obtaining fertility treatment services as a result of these special measures. These Regulations do not apply to embryos or gametes that are placed in storage after 1 July 2020. The ten year statutory storage period as set out in section 14(3) and (4) of the 1990 Act will apply in respect of those gametes or embryos.
- 7.9 Part 3 amends the 2009 Storage Regulations. Regulation 8 makes provision in respect of embryos while regulation 10 makes equivalent provision in respect of gametes. Part 3 provides for an extension to the statutory storage period (referred in the 2009 Storage Regulations as the ‘maximum storage period’) where the storage of gametes or embryos has previously been extended under the 2009 Storage Regulations, but the persons specified in the regulations are unable, due to a reason relating to coronavirus, to obtain a further written opinion from a registered medical practitioner within the ten year period required by the 2009 Storage Regulations. In such situations, the maximum storage period may be extended, on one occasion only, so that it begins on the date the gametes or embryos were first placed in storage and ends twelve years from the date of the most recent written opinion (an extension of two years, referred to in these Regulations as “the extended storage period”). In order to benefit from this extension, the gametes or embryos must be stored in a licensed premises on 1 July 2020 and the persons specified in the regulations need to provide consent for the

relevant gametes or embryos to remain in storage for at least the extended storage period.

- 7.10 The purpose of the amendments to the 2009 Storage Regulations is to ensure that those who need to obtain a further written opinion from a registered medical practitioner in order to further extend the statutory storage period for their embryos or gametes but are unable to do so due to a reason relating to coronavirus, have an additional two years in which to do so. These Regulations do not require a person to provide specific evidence to demonstrate that they are unable to obtain a further written opinion from a registered medical practitioner. Instead, it is intended that most persons will be able to self-certify that they are unable to obtain a further written opinion for a reason relating to coronavirus, especially if they do so when the effects of the special measures taken in response to COVID-19 are still having a wider impact in the United Kingdom. Guidance will be issued to clinics by the HFEA in relation to this.
- 7.11 No amendments are made to the 2009 Storage Regulations in relation to persons who have not previously obtained a written opinion from a registered medical practitioner in relation to premature infertility but intend to do so in the future. Such persons will be able to benefit from the two year extension to the statutory storage period in regulations 3 or 4 of these Regulations and may, during that extended period, obtain any necessary written opinion.
- 7.12 In order to ensure that after the statutory storage period has been extended under these Regulations, the 2009 Storage Regulations continue to work effectively, modifications to the meaning of “relevant period” in regulations 3 and 4 of the 2009 Storage Regulations have been made in regulations 7 and 9 of these Regulations, respectively. The ‘relevant period’ is the time during which a written opinion must be obtained in order to extend the statutory storage period by ten years due to premature infertility. It is currently defined as meaning ten years after the date the gamete or embryo was first placed in storage or, if later, ten years from the date that the most recent written opinion was given. Where the statutory storage period has been extended under these Regulations, the meaning of ‘relevant period’ has been modified in certain circumstances to reflect the extended storage period of twelve years. This will ensure that where a person obtains further written opinions after the statutory storage period has been extended under these Regulations further extensions of ten years will continue to be available to specified persons under the 2009 Storage Regulations, up to a maximum of fifty five years.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

- 8.1 This instrument does not relate to withdrawal from the European Union/ trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

- 9.1 Not applicable.

10. Consultation outcome

- 10.1 No public consultation has taken place in relation to this instrument.
- 10.2 A public consultation was completed on 5 May 2020 which was asked for views about possible changes the statutory storage limits in the 1990 Act. The Government will be analysing the consultation responses, which will inform a possible future

changes to the policy position. Any permanent change would need to be made by primary legislation.

11. Guidance

- 11.1 Clinics will receive guidance from the HFEA about the impact and implications of this instrument and any immediate action that needs to be taken to ensure that appropriate written consent is in place in respect of any stored gametes or embryos. The HFEA will also update its Code of Practice in due course.

12. Impact

- 12.1 The impact on business, charities or voluntary bodies is minimal as this instrument will only affect centres licensed to store gametes or embryos, and patients who voluntarily store.
- 12.2 The impact on the public sector is minimal as this instrument only affect centres licensed to store gametes or embryos, and patients who voluntarily store. Some storage is currently funded by the NHS, however, extended storage is most often funded by the patient on a voluntary basis. We have estimated that this benefit at least equals the cost of storage, as clearly those who choose to store believe that the benefits exceed any costs that they have to pay.
- 12.3 An Impact Assessment has not been prepared for this instrument because of the very limited impact on business, they provide immediate benefit persons with gametes or embryos in storage and it is in the public interest for the new rules to come into force as soon as possible.

13. Regulating small business

- 13.1 The instrument will apply to small businesses, as around 60% of fertility clinics are private. The changes that will be made by the instrument should have only a minimal effect on clinics. Storage is voluntary, and any increased costs associated with storage will be met by the people who choose to store and in some cases by the NHS.

14. Monitoring & review

- 14.1 The impact of the temporary extension will be taken into account as part of the review of consultation responses to the public consultation about permanent changes to the statutory storage limit.

15. Contact

- 15.1 Steve Pugh at the Department of Health and Social Care. Telephone: 0207 210 4350 or email: steve.pugh@dhsc.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Mark Davies at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Lord Bethell at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.