

2020 No. 566

HUMAN FERTILISATION AND EMBRYOLOGY

**The Human Fertilisation and Embryology (Statutory Storage
Period for Embryos and Gametes) (Coronavirus) Regulations
2020**

<i>Made</i> - - - -	<i>2nd June 2020</i>
<i>Laid before Parliament</i>	<i>3rd June 2020</i>
<i>Coming into force</i> - -	<i>1st July 2020</i>

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 14(5) and 45(1), (3) and (3A) of the Human Fertilisation and Embryology Act 1990(a).

PART 1

General

Citation and coming into force

1. These Regulations may be cited as the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 and come into force on 1st July 2020.

Interpretation

2. In these Regulations—

“the 2009 Regulations” means the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009(b);

“the Act” means the Human Fertilisation and Embryology Act 1990;

“the relevant persons” means the two people whose gametes were used to bring about the creation of an embryo.

(a) c.37. Section 14(5) was amended by section 15(1) and (5) of, and Schedule 8 to, the Human Fertilisation and Embryology Act 2008 (c.22) (“the 2008 Act”). Section 45 was amended, so far as relevant, by section 30(4) and (5) of the 2008 Act. Section 45(1) provides for the Secretary of State to make regulations for any purpose for which regulations may be made under the 2008 Act. *See* section 45(6) for the definition of “regulations”.

(b) S.I. 2009/1582, as amended by S.I. 2009/2581.

PART 2

Extension of the statutory storage period for embryos and gametes

Extension of the statutory storage period for embryos

3.—(1) Subject to regulations 3 and 3A of the 2009 Regulations, in the circumstances specified in paragraph (2), section 14(4) of the Act (conditions of storage licences) shall have effect as if for ten years there were substituted twelve years.

(2) The circumstances referred to in paragraph (1) are that—

- (a) the embryo in question is, on 1st July 2020, being stored on premises to which a licence under paragraph 1 (licences for treatment), 2 (licences for storage) or 3 (licences for research) of Schedule 2 (activities for which licences may be granted) to the Act relates; and
- (b) the relevant persons have consented in writing, whether before, on or after 1st July 2020, to the embryo being stored for at least twelve years.

Extension of the statutory storage period for gametes

4.—(1) Subject to regulations 4 and 4A of the 2009 Regulations, in the circumstances specified in paragraph (2), section 14(3) of the Act (conditions of storage licences) shall have effect as if for ten years there were substituted twelve years.

(2) The circumstances referred to in paragraph (1) are that—

- (a) the gamete in question is, on 1st July 2020, being stored on premises to which a licence under paragraph 1, 2 or 3 of Schedule 2 to the Act relates; and
- (b) the person who provided the gamete has consented in writing, whether before, on or after 1st July 2020, to the gamete being stored for at least twelve years.

PART 3

Amendments to the 2009 Regulations

5. The 2009 Regulations are amended in accordance with regulations 6 to 10.

Amendment of regulation 2 (interpretation)

6. In regulation 2—

- (a) after the definition of “the 1996 Regulations” insert—

““the 2020 Regulations” means the Human Fertilisation (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020;”;
- (b) after the definition of “the Act” insert—

““coronavirus” means severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2);”.

Amendment of regulation 3 (extension of statutory storage period for premature infertility)

7.—(1) In regulation 3(1)(a), for “For the purpose of” substitute “Subject to paragraphs (6) and (7), for the purpose of”.

(a) Regulation 3 was amended by S.I. 2009/2581.

- (2) In regulation 3(2), after “subject to paragraph (4)” insert “and regulation 3A”.
- (3) After regulation 3(5) insert—
- “(6) Where the statutory storage period for an embryo has been extended under regulation 3 of the 2020 Regulations, paragraph (1) applies as if “relevant period” means—
- (a) where the statutory storage period for the embryo has not previously been extended under paragraph (2), twelve years from the date that the embryo in question was first placed in storage;
 - (b) where the statutory storage period for the embryo has previously been extended under paragraph (2)—
 - (i) twelve years from the date that the embryo in question was first placed in storage, or
 - (ii) if later, ten years from the date that the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).
- (7) Where the statutory storage period for an embryo has been extended under regulation 3A, paragraph (1) applies as if “relevant period” means—
- (a) where the most recent previous written opinion given under sub-paragraph (b) of paragraph (3) was given before 1st July 2020, twelve years from the date of that opinion;
 - (b) where the most recent previous written opinion given under sub-paragraph (b) of paragraph (3) was given on or after 1st July 2020, ten years from the date of that opinion.”.

New regulation 3A (extension of statutory storage period for premature infertility for a reason relating to coronavirus)

8. After regulation 3 insert—

“Extension of statutory storage period for premature infertility for a reason relating to coronavirus

3A.—(1) In the circumstances specified in paragraph (2), the maximum storage period for an embryo shall, subject to paragraph (3), be the period beginning with the date on which the embryo was first placed into storage and ending twelve years after the date of the most recent written opinion given under paragraph (3)(b) of regulation 3 (“the extended storage period”).

- (2) The circumstances referred to in paragraph (1) are that—
- (a) the embryo in question is, on 1st July 2020, being stored, for the provision of treatment services, on premises to which a licence under paragraph 1 or 2 of Schedule 2 to the Act relates;
 - (b) a registered medical practitioner has, before 1st July 2020, given a written opinion under paragraph (3)(b) of regulation 3;
 - (c) neither of the relevant persons nor, where they are not one of those persons, the person to be treated, is, for a reason relating to coronavirus, able to obtain a further written opinion within ten years from the date that the written opinion referred to in sub-paragraph (b) was given;
 - (d) the relevant persons have consented in writing, whether before, on or after 1st July 2020, to the embryo being stored for at least the extended storage period for the provision of treatment services; and
 - (e) the statutory storage period for the embryo has not previously been extended under paragraph (1).

(3) Where the maximum storage period calculated in accordance with paragraph (1) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.”.

Amendment of regulation 4 (extension of statutory storage period for premature infertility)

9.—(1) In regulation 4(1)(a), for “For the purpose of” substitute “Subject to paragraphs (5) and (6), for the purpose of”.

(2) In regulation 4(2), after “subject to paragraph (4)” insert “and regulation 4A”.

(3) After regulation 4(4) insert—

“(5) Where the statutory storage period for a gamete has been extended under regulation 4 of the 2020 Regulations, paragraph (1) applies as if “relevant period” means—

- (a) where the statutory storage period for the gamete has not previously been extended under paragraph (2), twelve years from the date that the gamete in question was first placed in storage;
- (b) where the statutory storage period for the gamete has previously been extended under paragraph (2)—
 - (i) twelve years from the date the gamete in question was first placed in storage, or
 - (ii) if later, ten years from the date that the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(6) Where the statutory storage period for a gamete has been extended under regulation 4A, paragraph (1) applies as if “relevant period” means—

- (a) where the most recent previous written opinion given under sub-paragraph (b) of paragraph (3) was given before 1st July 2020, twelve years from the date of that opinion;
- (b) where the most recent previous written opinion given under sub-paragraph (b) of paragraph (3) was given on or after 1st July 2020, ten years from the date of that opinion.”.

New regulation 4A (extension of statutory storage period for premature infertility for a reason relating to coronavirus)

10. After regulation 4 insert—

“Extension of statutory storage period for premature infertility for a reason relating to coronavirus

4A.—(1) In the circumstances specified in paragraph (2), the maximum storage period for a gamete shall, subject to paragraph (3), be the period beginning with the date on which the gamete was first placed into storage and ending twelve years after the date of the most recent written opinion given under paragraph (3)(b) of regulation 4 (“the extended storage period”).

(2) The circumstances referred to in paragraph (1) are that—

- (a) the gamete in question is, on 1st July 2020, being stored, for the provision of treatment services, on premises to which a licence under paragraph 1 or 2 of Schedule 2 to the Act relates;
- (b) a registered medical practitioner has, before 1st July 2020, given a written opinion under paragraph (3)(b) of regulation 4;

(a) Regulation 4 was amended by S.I. 2009/2581.

- (c) neither the person who provided the gamete nor, where they are not that person, the person to be treated, is, for a reason relating to coronavirus, able to obtain a further written opinion within ten years from the date that the written opinion referred to in sub-paragraph (b) was given;
 - (d) the person who provided the gamete has consented in writing, whether before, on or after 1st July 2020, to the gamete being stored for at least the extended storage period for the provision of treatment services; and
 - (e) the statutory storage period for the gamete has not previously been extended under paragraph (1).
- (3) Where the maximum storage period calculated in accordance with paragraph (1) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.”.

2nd June 2020

Matt Hancock
Secretary of State,
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations provide for embryos and gametes to be stored in certain circumstances for longer than the period of ten years (“the statutory storage period”) laid down by section 14(3) and (4) of the Human Fertilisation and Embryology Act 1990 (c.37) (“the Act”), as amended by the Human Fertilisation and Embryology Act 2008 (c.22).

Part 2 extends the statutory storage period for embryos and gametes to twelve years (an additional two years). Regulation 3 extends the statutory storage period in respect of embryos and regulation 4 provides for an equivalent extension in respect of gametes. Where embryos or gametes are stored on licenced premises on 1st July 2020 (the date these Regulations come into force) and such persons, as specified in the Regulations, provide consent, the relevant embryos or gametes may be kept in storage for twelve years from the date they were first placed in storage.

Part 3 amends the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 (S.I. 2009/1582) (“the 2009 Regulations”). The 2009 Regulations provide for embryos and gametes to be stored in certain circumstances for longer than the period of ten years laid down by section 14(3) and (4) of the Act, namely where, in the written opinion of a registered medical practitioner, one of the gamete providers or the person to be treated, is, or is likely to become, prematurely infertile. If the conditions in the 2009 Regulations are met, the statutory storage period may be extended for ten years from the date the registered medical practitioner provides a written opinion. Further extensions to the statutory storage period of ten years may be made if further written opinions from a registered medical practitioner are obtained within each ten year extension.

Part 3 provides that the statutory storage period for embryos (regulation 8) and gametes (regulation 10) may be extended so that it ends twelve years after the date of the most recent written opinion in certain circumstances. Regulations 7 and 9 respectively amend regulations 3 and 4 of the 2009 Regulations. The amendments ensure that specified persons who either obtain a written opinion for the first time or who obtain a further written opinion within the extended statutory storage period provided for in these Regulations, may, thereafter arrange for the relevant embryos or gametes to be stored for an additional ten years (under regulations 3 and 4 of the 2009 Regulations).

An impact assessment has not been prepared for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

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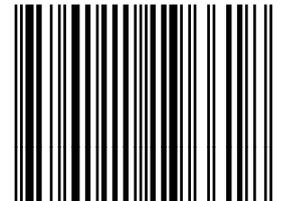
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