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STATUTORY INSTRUMENTS

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**2009 No. 1582**

**HUMAN FERTILISATION AND EMBRYOLOGY**

**The Human Fertilisation and Embryology (Statutory  
Storage Period for Embryos and Gametes) Regulations 2009**

<i>Made</i>	- - - -	<i>25th June 2009</i>
<i>Laid before Parliament</i>		<i>1st July 2009</i>
<i>Coming into force</i>	- -	<i>1st October 2009</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(1).

**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) Regulations 2009 and shall come into force on 1st October 2009.

**Interpretation**

2. In these Regulations—

“the 1991 Regulations” means the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991(2);

“the 1996 Regulations” means the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996(3);

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

“person to be treated” means—

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(1) 1990 c. 37 section 14(5) was amended by section 15(5) of the Human Fertilisation and Embryology Act 2008 c. 22 (“the 2008 Act”). Section 45 was amended 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 Act.

(2) S.I. No.1991/1540. There are no relevant amending instruments.

(3) S.I. No.1996/375. There are no relevant amending instruments.

- (a) the woman whom it is intended will be provided with treatment services<sup>(4)</sup> using the embryo or gamete in question;
  - (b) the woman who the embryo or gamete in question has been allocated to by a person to whom a licence applies<sup>(5)</sup>; or
  - (c) the man who the embryo or gamete in question has been allocated to by a person to whom a licence applies; and
- “the relevant persons” means the two people whose gametes were used to bring about the creation of an embryo.

## PART 2

### Embryos

#### **Extension of statutory storage period for premature infertility**

3.—(1) For the purpose of this regulation—

“relevant period” means ten years from the date that—

- (a) the embryo in question was first placed in storage; or
- (b) if later, the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(2) In the circumstances specified in paragraph (3), the statutory storage period for an embryo under section 14(4) of the Act<sup>(6)</sup> (conditions of storage licences) shall, subject to paragraph (4), be the period beginning with the date on which the embryo was first placed into storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3).

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

- (a) the relevant persons have consented in writing to the embryo in question being stored for a period in excess of ten years for the provision of treatment services; and
- (b) on any day within the relevant period a registered medical practitioner has given a written opinion that one of the relevant persons, or, where they are not one of those persons, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(4) Where the statutory storage period calculated in accordance with paragraph (2) would be greater than fifty five years, the statutory storage period for the purpose of that paragraph shall be fifty five years.

## PART 3

### Gametes

#### **Extension of statutory storage period for premature infertility**

4.—(1) For the purpose of this regulation—

“relevant period” means ten years from the date that—

- (a) the gamete in question was first placed in storage; or

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<sup>(4)</sup> In these Regulations “treatment services” has the meaning given by section 2 of the Act.

<sup>(5)</sup> In these Regulations “person to whom a licence applies” has the meaning given by section 17(2) of the Act.

<sup>(6)</sup> Section 14(4) was amended by section 15(3) of the 2008 Act.

- (b) if later, the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).
- (2) In the circumstances specified in paragraph (3), the statutory storage period for a gamete under section 14(3) of the Act (conditions of storage licences) shall, subject to paragraph (4), be the period beginning with the date on which the gamete was first placed into storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3).
- (3) The circumstances referred to in paragraph (2) are that—
  - (a) the person who provided the gamete in question has consented in writing to the gamete being stored for a period in excess of ten years for the provision of treatment services; and
  - (b) on any day within the relevant period a registered medical practitioner has given a written opinion that the person who provided the gamete or, where they are not that person, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.
- (4) Where the statutory storage period calculated in accordance with paragraph (2) would be greater than fifty five years, the statutory storage period for the purpose of that paragraph shall be fifty five years.

## PART 4

### Transitionals, Revocations and Saving

#### **Transitional provision for embryos: original storage period**

5.—(1) In regulations 5 and 6 “original storage period” means the five year statutory storage period under section 14(4) of the Act prior to its amendment by the Human Fertilisation and Embryology Act 2008(7).

(2) Except where regulation 6 applies, this paragraph applies to an embryo that is in storage on the date that these Regulations come into force in relation to which the original storage period has not expired.

- (3) Where paragraph (2) applies the statutory storage period for the embryo in question shall be—
  - (a) subject to paragraph (6), where the circumstances in paragraph (4) are met, the period beginning with the date on which the embryo was first placed in storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (4); or
  - (b) ten years where those circumstances are not met.
- (4) The circumstances referred to in sub-paragraph (a) of paragraph (3) are that—
  - (a) the relevant persons have consented in writing whether before or after the coming into force of these Regulations to the embryo in question being stored for a period in excess of ten years for the provision of treatment services; and
  - (b) on any day within the relevant period, but after the coming into force of these Regulations, a registered medical practitioner has given a written opinion that one of the relevant persons, or, where they are not one of those persons, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.
- (5) For the purposes of sub-paragraph (b) of paragraph (4), “the relevant period” means—
  - (a) five years from the date that the embryo in question was first placed in storage; or

(b) if later, ten years from the date the most recent previous written opinion was given under sub-paragraph (b) of paragraph (4).

(6) Where the statutory storage period calculated in accordance with sub-paragraph (a) of paragraph (3) would be greater than fifty five years, the statutory storage period for the purpose of that sub-paragraph shall be fifty five years.

#### **Transitional provision for embryos: extended storage period**

6.—(1) This paragraph applies to an embryo that is in storage on the date that these Regulations come into force in relation to which a storage period in excess of the original storage period applies by virtue of the 1996 Regulations (“the extended storage period”).

(2) Where paragraph (1) applies the statutory storage period for the embryo in question shall be—

(a) subject to paragraph (5), where the circumstances in paragraph (3) are met, the period beginning with the date on which the embryo was first placed in storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3); or

(b) the extended storage period where those circumstances are not met.

(3) The circumstances referred to in sub-paragraph (a) of paragraph (2) are that—

(a) the relevant persons have consented in writing whether before or after the coming into force of these Regulations to the embryo in question being stored for a period in excess of ten years for the provision of treatment services; and

(b) on any day within the relevant period, but after the coming into force of these Regulations, a registered medical practitioner has given a written opinion that one of the relevant persons, or, where they are not one of those persons, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(4) For the purposes of sub-paragraph (b) of paragraph (3), “the relevant period” means—

(a) the extended storage period; or

(b) if later, ten years from the date the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(5) Where the statutory storage period calculated in accordance with sub-paragraph (a) of paragraph (2) would be greater than fifty five years, the statutory storage period for the purpose of that sub-paragraph shall be fifty five years.

#### **Transitional provision for gametes: statutory storage period**

7.—(1) Except where regulation 8 applies, this paragraph applies to any gamete that is in storage on the date that these Regulations come into force.

(2) Where paragraph (1) applies, the statutory storage period for any gamete shall be—

(a) subject to paragraph (5), where the circumstances in paragraph (3) are met, the period beginning with the date on which the gamete was first placed in storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3); or

(b) ten years where those circumstances are not met.

(3) The circumstances referred to in sub-paragraph (a) of paragraph (2) are that—

(a) the person who provided the gamete in question has consented in writing, whether before or after the coming into force of these Regulations, to the gamete being stored for a period in excess of ten years for the provision of treatment services; and

- (b) on any day within the relevant period, but after the coming into force of these Regulations, a registered medical practitioner has given a written opinion that the gamete provider, or, where they are not that person, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(4) For the purposes of sub-paragraph (b) of paragraph (3), “the relevant period” means ten years from the date that—

- (a) the gamete in question was first placed in storage; or
- (b) if later, the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(5) Where the statutory storage period calculated in accordance with sub-paragraph (a) of paragraph (2) would be greater than fifty five years, the statutory storage period for the purpose of that paragraph shall be fifty five years.

### **Transitional provision for gametes: extended storage period**

**8.—**(1) This paragraph applies to any gamete that is in storage on the date that these Regulations come into force in relation to which a storage period in excess of ten years applies by virtue of the 1991 Regulations (“the extended storage period”).

(2) Where paragraph (1) applies the statutory storage period for the gamete shall be—

- (a) subject to paragraph (5), where the circumstances in paragraph (3) are met, the period beginning with the date on which the gamete was first placed in storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (b) of paragraph (3); or
- (b) the extended storage period where those circumstances are not met.

(3) The circumstances referred to in sub-paragraph (a) of paragraph (2) are that—

- (a) the person who provided the gamete in question has consented in writing, whether before or after the coming into force of these Regulations, to the gamete being stored for a period in excess of ten years for the provision of treatment services; and
- (b) on any day within the relevant period, but after the coming into force of these Regulations, a registered medical practitioner has given a written opinion that the gamete provider, or, where they are not that person, the person to be treated, is prematurely infertile or is likely to become prematurely infertile.

(4) For the purposes of sub-paragraph (b) of paragraph (3), “the relevant period” means—

- (a) the extended storage period; or
- (b) if later, ten years from the date the most recent previous written opinion was given under sub-paragraph (b) of paragraph (3).

(5) Where the statutory storage period calculated in accordance with sub-paragraph (a) of paragraph (2) would be greater than fifty five years, the statutory storage period for the purpose of that paragraph shall be fifty five years.

### **Revocations and savings**

**9.—**(1) Subject to paragraphs (2) and (3) the 1991 Regulations and the 1996 Regulations are revoked.

- (2) The 1991 Regulations shall continue to have effect for the purposes of regulation 8.
- (3) The 1996 Regulations shall continue to have effect for the purposes of regulation 6.

Signed by authority of the Secretary of State for Health.

25th June 2009

*Gillian Merron*  
Minister of State,  
Department of Health

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## 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 10 years laid down by section 14(3) and (4) of the Human Fertilisation and Embryology Act 1990 (“the 1990 Act”) as amended by the Human Fertilisation and Embryology Act 2008.

Regulation 3 extends the statutory storage period for an embryo if the people whose gametes were used to create that embryo consent to storage of the embryo for more than 10 years, and, in the written opinion of a registered medical practitioner one of the gamete providers, the woman who is to be treated with the embryo, or the man or woman the embryo is allocated to is prematurely infertile or is likely to become prematurely infertile. If these conditions are met the statutory storage period is extended for another ten years from the date the registered medical practitioner provides the written opinion. Further extensions to the statutory storage period of ten years can then be made if further written opinions from a registered medical practitioner are obtained within each ten year extension. The total storage period for any embryo cannot exceed fifty five years.

Regulation 4 extends the storage period for a gamete if the gamete provider consents to storage of the gamete for more than 10 years, and, in the written opinion of a registered medical practitioner, the gamete provider, the woman who is to be treated with the gamete, or the man or woman the gamete is allocated to is prematurely infertile or is likely to become prematurely infertile. If these conditions are met the statutory storage period is extended for another ten years from the date the registered medical practitioner provides the written opinion. Further extensions to the statutory storage period can then be made if further written opinions from a registered medical practitioner are obtained within each ten year extension. The total storage period for any gamete cannot exceed fifty five years.

Regulations 5 to 8 make transitional provision for embryos and gametes in storage at the date of the coming into force of the Regulations.

Regulation 9 revokes the existing regulations made under the 1990 Act and makes saving provision for the purposes of regulations 6 and 8.