

*Draft Regulations laid before Parliament under section 45(4) of the Human Fertilisation and Embryology Act 1990, for approval by resolution of each House of Parliament.*

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DRAFT STATUTORY INSTRUMENTS

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**2015 No. 0000**

**HUMAN FERTILISATION AND EMBRYOLOGY**

The Human Fertilisation and Embryology  
(Mitochondrial Donation) Regulations 2015

*Made* - - - - *\*\*\**  
*Coming into force* - - *29th October 2015*

These Regulations are made by the Secretary of State in exercise of the powers conferred by sections 3ZA(5) and (6), 31ZA(2)(a), 35A and 45(1) and (3A) of the Human Fertilisation and Embryology Act 1990(1).

A draft of this instrument has been approved by resolution of each House of Parliament pursuant to section 45(4) of that Act.

**PART 1**

**Introductory Provisions**

**Citation and commencement**

1. These Regulations may be cited as the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 and shall come into force on 29th October 2015.

**Interpretation**

2.—(1) In these Regulations “the Act” means the Human Fertilisation and Embryology Act 1990.

(2) In these Regulations “polar body nuclear DNA” means any nuclear DNA located in a polar body.

(3) In these Regulations a reference to the removal of any nuclear DNA (including polar body nuclear DNA) includes a reference to the removal of any material which is necessarily removed along with that DNA, and such material may include any associated organelles.

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(1) 1990 c. 37. Sections 3ZA(5) and (6), 31ZA(2)(a), 35A and 45(3A) were inserted by sections 3(5), 24, 26 and 30 of the Human Fertilisation and Embryology Act 2008 (c. 22) (“the 2008 Act”). Section 3ZA(6) is cited for the meaning of “prescribed”.

(4) For the purposes of these Regulations, the following are to be treated as removed from an egg—

- (a) any polar body nuclear DNA which is destroyed while still located in the egg; and
- (b) any material which is necessarily destroyed along with that DNA, and such material may include any associated organelles.

(5) In these Regulations a reference to the insertion of nuclear DNA includes a reference to the insertion of any material which is necessarily inserted along with that DNA, and such material may include any associated organelles.

## PART 2

### Permitted eggs and permitted embryos

#### Permitted egg

3. An egg (“egg P”) is a permitted egg for the purposes of section 3(2)(b)(2) of the Act if—
- (a) egg P results from the application of the process specified in regulation 4 to two eggs, each of which—
    - (i) is a permitted egg as defined in section 3ZA(2)(3) of the Act (not an egg which is a permitted egg by virtue of these regulations), and
    - (ii) was extracted from the ovaries of a different woman;
  - (b) that process has been applied to those eggs in the circumstances specified in regulation 5; and
  - (c) there have been no alterations in the nuclear or mitochondrial DNA of egg P since egg P was created by means of the application of that process.

#### Permitted egg: process

- 4.—(1) The process referred to in regulation 3(a) consists of the following two steps.
- (2) In step 1—
- (a) either—
    - (i) all the nuclear DNA of an egg (“egg A”) is removed, or
    - (ii) all the nuclear DNA of egg A other than polar body nuclear DNA is removed; and
  - (b) either—
    - (i) all the nuclear DNA of another egg (“egg B”) is removed, or
    - (ii) all the nuclear DNA of egg B other than polar body nuclear DNA is removed.
- (3) In step 2 all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.

#### Permitted egg: circumstances

5. The circumstances referred to in regulation 3(b) are that—
- (a) the Authority has issued a determination that—

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(2) Section 3(2) was substituted by section 3(2) of the 2008 Act.

(3) Section 3ZA was inserted by section 3(5) of the 2008 Act.

- (i) there is a particular risk that any egg extracted from the ovaries of a woman named in the determination may have mitochondrial abnormalities caused by mitochondrial DNA; and
  - (ii) there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease; and
- (b) egg B was extracted from the ovaries of the woman so named.

### **Permitted embryo**

6. An embryo (“embryo P”) is a permitted embryo for the purposes of section 3(2)(a) of the Act if—

- (a) embryo P results from the application of the process specified in regulation 7 to two embryos, each of which—
  - (i) is a permitted embryo as defined in section 3ZA(4) of the Act (not an embryo which is a permitted embryo by virtue of these regulations), and
  - (ii) was created by the fertilisation of a permitted egg as defined in section 3ZA(2) of the Act (not an egg which was a permitted egg by virtue of these regulations) extracted from the ovaries of a different woman;
- (b) that process has been applied to those embryos in the circumstances specified in regulation 8; and
- (c) since embryo P was created by means of the application of that process—
  - (i) there have been no alterations in the nuclear or mitochondrial DNA of any cell of embryo P, and
  - (ii) no cell has been added to embryo P other than by the division of embryo P’s own cells.

### **Permitted embryo: process**

- 7.—(1) The process referred to in regulation 6(a) consists of the following two steps.
- (2) In step 1—
- (a) either—
    - (i) all the nuclear DNA of an embryo (“embryo A”) is removed, or
    - (ii) all the nuclear DNA of embryo A other than polar body nuclear DNA is removed; and
  - (b) either—
    - (i) all the nuclear DNA of another embryo (“embryo B”) is removed, or
    - (ii) all the nuclear DNA of embryo B other than polar body nuclear DNA is removed.
- (3) In step 2 all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.

### **Permitted embryo: circumstances**

8. The circumstances referred to in regulation 6(b) are that—
- (a) the Authority has issued a determination that—
    - (i) there is a particular risk that any embryo which is created by the fertilisation of an egg extracted from the ovaries of a woman named in the determination may have mitochondrial abnormalities caused by mitochondrial DNA; and

- (ii) there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease; and
- (b) embryo B was created by the fertilisation of an egg extracted from the ovaries of the woman so named.

### **Supplemental provision – licences**

9.—(1) Any reference to a permitted egg in a licence whenever issued does not include an egg which is a permitted egg for the purposes of section 3(2) of the Act by virtue of regulation 3 unless express provision is made in the licence to that effect.

(2) Any reference to a permitted embryo in a licence whenever issued does not include an embryo which is a permitted embryo for the purposes of section 3(2) of the Act by virtue of regulation 6 unless express provision is made in the licence to that effect.

## **PART 3**

### **Related modifications and amendments**

#### **Modification of certain enactments for cases where mitochondrial donation has occurred**

10. Regulations 11 to 18 (which make modifications to the Act and the Human Fertilisation and Embryology Act 2008) have effect in relation to cases where—

- (a) an egg has been created which is a permitted egg for the purposes of section 3(2) of the Act by virtue of regulation 3, or
- (b) an embryo has been created which is a permitted embryo for those purposes by virtue of regulation 6.

#### **Modification of section 31ZA of the Act**

11. In a case where this regulation has effect, section 31ZA of the Act<sup>(4)</sup> applies as if—

- (a) for the heading there were substituted “Request for information as to genetic parentage or mitochondrial donors etc”;
- (b) in subsection (1) at the end there were inserted “or (2A)”;
- (c) after subsection (2) there were inserted—

“(2A) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person is the applicant’s mitochondrial donor, and if it does show that, giving the applicant the following information contained in the register—

- (a) the screening tests carried out on the mitochondrial donor and information on that donor’s personal and family medical history,
- (b) matters contained in any description of the mitochondrial donor as a person which that donor has provided, and
- (c) any additional matter which the mitochondrial donor has provided with the intention that it be made available to a person who requests information under this section,

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(4) Section 31ZA was inserted by section 24 of the 2008 Act.

but not giving any information which may identify the mitochondrial donor or any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor, by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.”;

(d) after subsection (3) there were inserted—

“(3A) The Authority must comply with a request under subsection (2A) if—

- (a) the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, and
- (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.”;

(e) in subsection (5), after “Regulations” there were inserted “under subsection (2)(a)”;

(f) after subsection (7) there were inserted—

“(8) In this section and sections 31ZB to 31ZE—

“mitochondrial donor-conceived person” means a person who was or may have been born in consequence of treatment services using—

- (a) an egg which is a permitted egg for the purposes of section 3(2) by virtue of regulations under section 3ZA(5), or
- (b) an embryo which is a permitted embryo for those purposes by virtue of such regulations;

the “mitochondrial donor” in respect of a person who was or may have been born in consequence of treatment services using such a permitted egg or such a permitted embryo is the person whose mitochondrial DNA (but not nuclear DNA) was used to create that egg or embryo.”.

### **Modification of section 31ZB of the Act**

**12.** In a case where this regulation has effect, section 31ZB of the Act<sup>(5)</sup> applies as if after subsection (6) there were inserted—

“(6A) For the purposes of this section, in a case where the information contained in the register shows that the applicant is a mitochondrial donor-conceived person, the applicant is not a person who, but for the relevant statutory provisions, would or might be related to—

- (a) the applicant's mitochondrial donor, or
- (b) any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor.”.

### **Modification of section 31ZC of the Act**

**13.** In a case where this regulation has effect, section 31ZC of the Act<sup>(6)</sup> applies as if—

- (a) for the heading there were substituted “Requests for information under section 31ZA: informing donors”;
- (b) after subsection (1) there were inserted—

“(1A) Where—

- (a) the Authority has received from a person (“the section 31ZA(2A) applicant”) a notice containing a request under section 31ZA(2A), and

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<sup>(5)</sup> Section 31ZB was inserted by section 24 of the 2008 Act.

<sup>(6)</sup> Section 31ZC was inserted by section 24 of the 2008 Act.

- (b) compliance by the Authority with its duty under that section has involved or will involve giving the section 31ZA(2A) applicant information relating to that applicant's mitochondrial donor,

the Authority must not notify the section 31ZA(2A) applicant's mitochondrial donor that the request has been made.”.

#### **Modification of section 31ZD of the Act**

**14.** In a case where this regulation has effect, section 31ZD of the Act<sup>(7)</sup> applies as if after subsection (3)(a) there were inserted—

- “(ab) the number of persons in respect of whom the donor is a mitochondrial donor,”.

#### **Modification of section 31ZE of the Act**

**15.** In a case where this regulation has effect, section 31ZE<sup>(8)</sup> of the Act applies as if after subsection (1) there were inserted—

“(1A) Subsection (1B) applies in respect of a mitochondrial donor-conceived person (“P”) and P's mitochondrial donor (“D”).

(1B) For the purposes of this section, D is not a person who would or might, but for the relevant statutory provisions, be the parent of P.”.

#### **Modification of paragraph 4 of Schedule 3 to the Act**

**16.** In a case where this regulation has effect, paragraph 4 of Schedule 3 to the Act applies as if—

- (a) after sub-paragraph (1) there were inserted—

“(1A) Sub-paragraph (1B) applies to a case where an egg is used in the process set out in regulation 4 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “egg A” and “egg B” have the same meanings in this paragraph as in that regulation).

(1B) The terms of the consent to that use of egg A or egg B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.”,

- (b) in sub-paragraph (2), for “sub-paragraph (3)” there were substituted “sub-paragraphs (3) to (3B)”, and

- (c) after sub-paragraph (3) there were inserted—

“(3A) Sub-paragraph (3B) applies to a case where an embryo is used in the process set out in regulation 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (and “embryo A” and “embryo B” have the same meanings in sub-paragraph (3B) as in that regulation).

(3B) The terms of the consent to that use of embryo A or embryo B cannot be varied, and such consent cannot be withdrawn, once all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.”.

#### **Modification of paragraph 22 of Schedule 3 to the Act**

**17.** In a case where this regulation has effect, paragraph 22 of Schedule 3 to the Act applies as if before sub-paragraph (1) there were inserted—

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(7) Section 31ZD was inserted by section 24 of the 2008 Act.

(8) Section 31ZE was inserted by section 24 of the 2008 Act.

“(A1) For the purposes of this Schedule, neither of the following is to be treated as a person whose gametes were used to create an embryo (“embryo E”)—

- (a) where embryo E is a permitted embryo by virtue of regulations under section 3ZA(5), the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of embryo E;
- (b) where embryo E has been created by the fertilisation of an egg which was a permitted egg by virtue of regulations under section 3ZA(5), the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.

(3B) For the purposes of this Schedule, in a case where an egg is permitted egg by virtue of regulations under section 3ZA(5) the egg is not to be treated as the egg of the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.”.

#### **Modification of section 54 of the Human Fertilisation and Embryology Act 2008**

**18.** In a case where this regulation has effect, section 54 of the Human Fertilisation and Embryology Act 2008 applies as if after subsection (1) there were inserted—

“(1A) For the purposes of this section, neither of the following is to be treated as a person whose gametes were used to create an embryo (“embryo E”)—

- (a) where embryo E is a permitted embryo by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of embryo E;
- (b) where embryo E has been created by the fertilisation of an egg which was a permitted egg by virtue of regulations under section 3ZA(5) of the 1990 Act, the person whose mitochondrial DNA (not nuclear DNA) was used to bring about the creation of that permitted egg.”.

#### **Consequential amendment of the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004**

**19.** In regulation 1(2) of the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004(9), in the definition of “applicant”, for “section 31ZA” substitute “section 31ZA(2)”.

Signed by authority of the Secretary of State for Health.

Date

*Name*  
Parliamentary Under-Secretary of State,  
Department of Health

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make provision to enable mitochondrial donation.

Part 2 provides for specified eggs and embryos, which contain donated mitochondria, to be permitted for use in assisted conception treatment under section 3(2) of the Human Fertilisation and Embryology Act 1990 (“the 1990 Act”) in certain circumstances. Regulations 4 and 7 prescribe the process that such an egg or embryo (egg or embryo “P”) must have undergone, which involves the removal of nuclear DNA from an egg or embryo which has abnormal mitochondria (egg or embryo “B”) and the insertion of this material into an enucleated egg or embryo which has healthy mitochondria (egg or embryo “A”). Regulations 3(c) and 6(c) ensure that no other alterations can be made to the resulting egg or embryo (egg or embryo “P”) after this process has taken place. Regulation 5 provides that, in relation to the use of the technique for an egg, the Human Fertilisation and Embryology Authority (“the HFEA”) must have issued a determination in relation to the woman from whose ovaries egg B was extracted that there is a particular risk that any egg extracted her ovaries may have mitochondrial abnormalities caused by mitochondrial DNA. Regulation 8 provides that, in relation to the use of the technique for an embryo, the HFEA must have issued a determination that there is a particular risk that any embryo created by the fertilisation of eggs from the woman whose egg was used to create embryo B may have mitochondrial abnormalities caused by mitochondrial DNA. The HFEA must also be satisfied that there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease. Regulation 9 makes supplemental provision to provide that existing treatment licences do not enable the use of eggs and embryos permitted under the regulations and to ensure that any new licence issued will require express provision to enable the use of such eggs or embryos. Treatment licences are granted under Schedule 2 to the 1990 Act.

Part 3 of the Regulations applies the 1990 Act with modifications to provide for cases where mitochondrial donation has taken place. Regulations 11 to 15 modify the information provisions in the 1990 Act to enable children born following mitochondrial donation to access limited, non-identifying, information about their mitochondrial donor. Provision is also made for a mitochondrial donor to access limited, non-identifying, information about children born from their donation, although they will not be notified about requests for information. The Regulations modify the 1990 Act to clarify that mitochondrial donors are not related to any children who were, or might have been, born following treatment services using their donation and therefore no provision is made to allow access to information in connection with entering into a marriage, civil partnership or intimate physical relationship, nor to access information about other children who share the same donor. Regulation 16 modifies the consent provisions in Schedule 3 to the 1990 Act to provide that where a person has consented to the use of their egg or embryo in mitochondrial donation such consent cannot be withdrawn once all the nuclear DNA from egg or embryo B is inserted into egg or embryo A. Further modifications are made by regulation 17 to ensure that for the purposes of the consent provisions in the 1990 Act the resulting egg or embryo is not to be treated as the egg or embryo of the person whose mitochondrial DNA was used to create it. Regulation 18 makes modifications to section 54 of the Human Fertilisation and Embryology Act 2008 to provide that where a child has been born following treatment services a person who donated mitochondria is not eligible to apply for a parental order on the basis of that donation alone.

Regulation 19 makes amendments to the limit the application of the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 so that they do not apply to information requests under the 1990 Act about mitochondrial donations.



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**Draft Legislation:** *This is a draft item of legislation. This draft has since been made as a UK Statutory Instrument: The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 No. 572*

A full impact assessment has been produced in relation to the Regulations and a copy is available from room 109 Department of Health, Richmond House, 79 Whitehall, London, SW1A 2NS and is published with the Explanatory Memorandum alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).