
DRAFT STATUTORY INSTRUMENTS

2015 No.

The Human Fertilisation and Embryology
(Mitochondrial Donation) Regulations 2015

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⁽¹⁾ 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,

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—

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

- “(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⁽²⁾ 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⁽³⁾ 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
 - (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.”.

(2) Section 31ZB was inserted by section 24 of the 2008 Act.

(3) Section 31ZC was inserted by section 24 of the 2008 Act.

Modification of section 31ZD of the Act

14. In a case where this regulation has effect, section 31ZD of the Act(4) 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(5) 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—

“(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;

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

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

- (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(6), in the definition of “applicant”, for “section 31ZA” substitute “section 31ZA(2)”.