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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.

DRAFT STATUTORY INSTRUMENTS

2009 No. 000

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Special Exemption) Regulations 2009

Made - - - - 2009

Coming into force - - 1st October 2009

The Secretary of State for Health makes these Regulations in exercise of the powers conferred by sections 43(1) and 45(1) to (3A) of the Human Fertilisation and Embryology Act 1990⁽¹⁾.

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

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Fertilisation and Embryology (Special Exemption) Regulations 2009 and shall come into force on 1st October 2009.

(2) In these Regulations—

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

“embryo” and “gametes” have the same meaning as they have by virtue of section 1(1), (4) and (6) of the Act in the other provisions of the Act (apart from section 4A)⁽²⁾.

Keeping and examining gametes and embryos in connection with crime

2.—(1) Subject to the provisions of this regulation a person to whom a licence applies⁽³⁾ or a person specified by the Authority may—

(a) keep or examine embryos; and

(1) 1990 c. 37. Section 45 was amended by section 30 of the Human Fertilisation and Embryology Act 2008 (c. 22) (“the 2008 Act”).

(2) Subsections (1) and (4) of section 1 were substituted by subsections (2) and (4) of section 1 of the 2008 Act. Subsection (6) of section 1 was inserted by subsection (5) of section 1 of the 2008 Act.

(3) “A person to whom a licence applies” is defined in section 17(2) of the Act.

- (b) store gametes,

in connection with the investigation of, or proceedings for, an offence under the Act.

- (2) This regulation applies only to embryos and gametes—

- (a) of which the Authority has taken possession; or
- (b) which are being or have been transferred from the person by whom they were being kept to another person in accordance either with directions(4) or with other arrangements made by the Authority in connection with the investigation of, or proceedings for, an offence under the Act.

(3) Embryos and gametes to which this regulation applies shall be kept or examined in accordance with paragraphs (4), (5) and (6).

(4) Embryos and gametes shall be kept so as to secure, so far as reasonably practicable, that their condition does not deteriorate.

- (5) Where embryos or gametes are kept or examined in any place where—

- (a) any activity governed by the Act is carried out in pursuance of a licence; or
- (b) gametes are stored under regulation 3,

the containers of embryos or gametes to which this regulation applies shall be labelled in such a way as to make them easily distinguishable from containers of embryos or gametes kept in pursuance of a licence or referred to in sub-paragraph (b).

(6) Embryos and gametes shall be kept or examined in such conditions as are reasonable to secure that access to them is denied to persons other than those referred to in paragraph (1) who are concerned with the particular investigation or proceedings in connection with which those embryos or gametes are being kept or examined.

Storage of gametes for other purposes

3.—(1) Subject to the provisions of this regulation, a person may store gametes which are to be used only for a purpose or purposes falling within paragraph (2), but only in so far as such purposes do not consist of or include treatment services(5) or any purpose falling within paragraph (3).

- (2) A purpose falls within this paragraph if it consists of—

- (a) research on gametes;
- (b) the development or testing of pharmaceutical or contraceptive products; or
- (c) teaching requiring the use of gametes.

- (3) A purpose falls within this paragraph if it consists of or includes any of the following—

- (a) the use of gametes in any mixing of live egg and live sperm whether human or not;
- (b) the use of gametes in bringing about the creation of an embryo;
- (c) the use of gametes in bringing about the creation of a human admixed embryo(6);
- (d) any use of gametes which could not be authorised by a licence;
- (e) the supply of gametes to any person to whom a licence applies for use in any activity authorised by that licence;

(4) See sections 23 and 24 of the Act.

(5) “Treatment services” are defined in section 2(1) of the Act.

(6) “Human admixed embryo” is defined in section 4A(6) to (12) of the Act. Section 4A was inserted into the Act by subsection (2) of section 4 of the 2008 Act.

(f) the supply of gametes to any person for money or other benefit unless the giving of the money or other benefit is authorised by directions in the case of gametes supplied in pursuance of a licence; or

(g) the export of gametes from the United Kingdom.

(4) Gametes for the supply of which a person has given money or other benefit may not be stored by that person under this regulation unless the giving of the money or other benefit was authorised by directions in the case of gametes obtained in pursuance of a licence.

(5) The conditions in paragraphs (6), (7) and (8) shall apply to the storage of gametes under this regulation.

(6) Where gametes are stored in any place where—

(a) any activity governed by the Act is carried out in pursuance of a licence; or

(b) embryos or gametes are kept or examined under regulation 2,

the containers of gametes stored under this regulation shall be labelled in such a way as to make them easily distinguishable from containers of embryos or gametes kept in pursuance of a licence or referred to in sub-paragraph (b).

(7) Access to gametes shall be limited to persons participating in the activities specified in paragraph (2), and (in the case of teaching) their students, but only under the supervision of their teacher.

(8) Gametes shall be stored in such conditions as are reasonable to secure that access to them is denied to persons other than those referred to in paragraph (7).

Revocation

4. The Human Fertilisation and Embryology (Special Exemption) Regulations 1991(7) are revoked.

Signed by authority of the Secretary of State for Health

Date

Name
Minister of State,
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations provide for two exceptions to the general rule that any person keeping or using human embryos, or storing human gametes, may do so only in accordance with a licence from the Human Fertilisation and Embryology Authority (“the Authority”).

The first exception, in regulation 2, applies to the keeping or examination of embryos, or the storing of gametes, in connection with the investigation of, or proceedings for, an offence under the Human Fertilisation and Embryology Act 1990. The exception provides that a person may keep or examine embryos, or store gametes, for that purpose without a licence from the Authority. Any such embryos or gametes will have been seized by the Authority or transferred to the place where they now are on the instructions of the Authority. They must if possible be kept in such a way that their condition does not deteriorate and must be distinctively labelled.

The second exception, in regulation 3, applies to the storing of gametes for the purpose of research on gametes, developing or testing pharmaceutical or contraceptive products, or teaching, provided they are not to be used for treatment services, mixing with eggs and sperm, bringing about the creation of a human embryo or human admixed embryo, or for any other purpose specified in regulation 3(3). The exception provides that a person may store gametes for these purposes without a licence if that person complies with the conditions set out in regulation 3(6), (7) and (8). No money or other benefit may be given or received for such gametes unless this was permitted (in the case of gametes stored under a licence) by directions given by the Authority (regulation 3(4)).

Regulation 4 revokes the Human Fertilisation and Embryology (Special Exemption) Regulations 1991. The new Regulations largely replicate the 1991 Regulations except in two respects. First, they take account of the following changes to the 1990 Act made by the Human Fertilisation and Embryology Act 2008: the new definitions of embryo and gametes; and the regulation of human admixed embryos. Secondly, the new Regulations make minor drafting changes to the 1991 Regulations.

A full regulatory impact assessment has not been produced for this instrument as no impact on the private or voluntary sectors is foreseen.